COPY

-Application

Medical Care PLLC

CN1505-018

SECTION A:
APPLICANT PROFILE

1. ***Name of Facility, Agency, or Institution***

Medical Care, PLLC **Name**		
1500 West Elk Avenue **Street or Route**		Carter **County**
Elizabethton **City**	TN **State**	37643 **Zip Code**

2. ***Contact Person Available for Responses to Questions***

Rachel C. Nelley **Name**		Attorney **Title**	
Farris Bobango PLC **Company Name**		rnelley@farris-law.com **Email address**	
618 Church Street, Suite 300 **Street or Route**	Nashville **City**	TN **State**	37219 **Zip Code**
Attorney **Association with Owner**	615-726-1200 **Phone Number**		615-726-1776 **Fax Number**

3. ***Owner of the Facility, Agency or Institution***

Medical Care PLLC **Name**		(423) 431-0527 **Phone Number**
1500 West Elk Avenue **Street or Route**		Carter **County**
Elizabethton **City**	TN **State**	37643 **Zip Code**

4. ***Type of Ownership of Control (Check One)***

A. Sole Proprietorship
B. Partnership
C. Limited Partnership
D. Corporation (For Profit)
E. Corporation (Not-for-Profit)
F. Government (State of TN or Political Subdivision)
G. Joint Venture
H. Limited Liability Company
I. Other (Specify) PLLC
Organizational documentation is attached as Attachment A-4.

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

5. ***Name of Management/Operating Entity (If Applicable)***

Pine Palms Management, LLC
Name

401 E. Main Street
Street or Route

Washington
County

Johnson City
City

TN
State

37601
Zip Code

6. ***Legal Interest in the Site of the Institution (Check One)***

A. Ownership
B. Option to Purchase
C. Lease of 10 Years X
D. Option to Lease
E. Other (Specify) _____

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

A copy of the lease agreement (titled "MRI License Agreement") is attached as Attachment A, 6.

7. ***Type of Institution (Check as appropriate--more than one response may apply)***

A. Hospital
B. (Specify)_____ Ambulatory Surgical Treatment Center (ASTC),
C. Multi-Specialty
D. ASTC, Single Specialty
E. Home Health Agency
F. Hospice
G. Mental Health Hospital Mental Health Residential
H. Treatment Facility Mental Retardation Institutional Habilitation Facility (ICF/MR)
I. Nursing Home
J. Outpatient Diagnostic Center
K. Recuperation Center
L. Rehabilitation Facility
M. Residential Hospice
N. Non-Residential Methadone Facility
O. Birthing Center
P. Other Outpatient Facility (Specify)_____
Q. Other (Specify) Physician Office-Based MRI X

8. **Purpose of Review** ***(Check) as appropriate--more than one response may apply)***

A. New Institution
B. Replacement/Existing Facility
C. Modification/Existing Facility
D. Initiation of Health Care Service as defined in TCA § 68-11-1607(4) (Specify) MRI X
E. Discontinuance of OB Services
F. Acquisition of Equipment (Shared Lease) X
G. Change in Bed Complement [*Please note the type of change by underlining the appropriate response: Increase, Decrease, Designation, Distribution, Conversion, Relocation]*
H. Change of Location
I. Other (Specify)_____

9. **Bed Complement Data** N/A

Please indicate current and proposed distribution and certification of facility beds.

N/A.	*Current Beds Licensed*	**CON*	*Staffed Beds*	*Beds Proposed*	*TOTAL Beds at Completion*
A. Medical					
B. Surgical					
C. Long-Term Care Hospital					
D. Obstetrical					
E. ICU/CCU					
F. Neonatal					
G. Pediatric					
H. Adult Psychiatric					
I. Geriatric Psychiatric					
J. Child/Adolescent Psychiatric					
K. Rehabilitation					
L. Nursing Facility (non-Medicaid Certified)					
M. Nursing Facility Level 1 (Medicaid only)					
N. Nursing Facility Level 2 (Medicare only)					
O. Nursing Facility Level 2 (dually certified Medicaid/Medicare)					
P. ICF/MR					
Q. Adult Chemical Dependency					
R. Child and Adolescent Chemical Dependency					
S. Swing Beds					
T. Mental Health Residential Treatment					
U. Residential Hospice					
TOTAL					

10. **Medicare Provider Number:** 3373580
Certification Type: Physician Group Practice

11. **Medicaid Provider Number:** 1512986
Certification Type: Physician Group Practice

12. **If this is a new facility, will certification be sought for Medicare and/or Medicaid?**

N/A. Medical Care PLLC is certified for Medicare and TennCare.

13. **Identify all TennCare Managed Care Organizations/Behavioral Health Organizations (MCOs/BHOs) operating in the proposed service area.**

BlueCare, TennCare Select and United Healthcare Community Plan

Will this project involve the treatment of TennCare participants?

Yes.

If the response to this item is yes, please identify all MCOs/BHOs with which the applicant has contracted or plans to contract.

BlueCare, TennCare Select, Amerigroup TennCare and United Healthcare Community Plan

Discuss any out-of-network relationships in place with MCOs/BHOs in the area.

N/A.

NOTE: ***Section B*** **is intended to give the applicant an opportunity to describe the project and to discuss the need that the applicant sees for the project.** ***Section C*** **addresses how the project relates to the Certificate of Need criteria of Need, Economic Feasibility, and the Contribution to the Orderly Development of Health Care. Discussions on how the application relates to the criteria should not take place in this section unless otherwise specified.**

SECTION B: PROJECT DESCRIPTION

Please answer all questions on 8 1/2" x 11" white paper, clearly typed and spaced, identified correctly and in the correct sequence. In answering, please type the question and the response. All exhibits and tables must be attached to the end of the application in correct sequence identifying the questions(s) to which they refer. If a particular question does not apply to your project, indicate "Not Applicable (NA)" after that question.

I. Provide a brief executive summary of the project not to exceed two pages. Topics to be included in the executive summary are a brief description of proposed services and equipment, ownership structure, service area, need, existing resources, project cost, funding, financial feasibility and staffing.

Project Description

Medical Care, PLLC (the "Applicant" or "MedCare" or "the Practice"), a NCQA[1] certified level 3 Patient Centered Medical Home[2], is a multi-specialty medical practice with 17 physicians and 14 physician extenders in specialties that include family practice, general practice, internal medicine, general surgery, gynecology and pediatrics with office locations in Elizabethton, Hampton and Johnson City, in Tennessee[3]. The Practice is a family owned professional limited liability company whose members are Arnold Hopland, MD (33.33%), Jeffrey Hopland, MD (33.33%), and Kenneth Hopland, MD (33.33%). The physician owners are all duly licensed in Tennessee and practice at Medical Care, PLLC.

Pine Palms Management, LLC (formerly known as Medical Care, LLC), which owns all of the assets utilized by the medical practice of Medical Care, PLLC, including real estate and equipment, is also a closely held family business and manages the Practice. Its owners are Dr. Arnold Hopland, MD (20%), Steven Hopland (20%), Jeffrey Hopland, MD (20%), Jennifer Whaley (20%) and Kenny Hopland, MD (20%).

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[1] National Committee for Quality Assurance ("NCQA") is a private, 501(c)(3) not-for-profit organization which manages voluntary accreditation programs for individual physicians, health plans, and medical groups. In Tennessee, all plans contracting with TennCare (Medicaid) must be NCQA Accredited.

[2] Blue Cross Blue Shield (BCBS) of Tennessee is a formal sponsor of the NCQA Patient-Centered Medical Home ("PCMH") Recognition program. Level 3 designation by NCQA is the highest achievable recognition for a medical group. NCQA's Patient Centered Medical Home program recognizes physician practices that prioritize the strengthening of the physician-patient relationship, coordinate care for patients across multiple settings, and engage in a team approach to improving patient care.

[3] Medical Care, PLLC has offices in the following locations, all of which are within the service area:
1500 West Elk Ave, Elizabethton, TN 37643
401 East Main Street, Johnson City, TN 37601
437 Hwy 321, Hampton, TN 37658

The Practice proposes to enter into a shared services and equipment agreement with Mountain States Health Alliance d/b/a Sycamore Shoals Hospital ("the Hospital"), a Tennessee nonprofit corporation licensed as a hospital to block lease time to allow physicians of the Practice to utilize the MRI currently in operation at Sycamore Shoals Hospital.

The professional fees for the scans will be billed by the radiologists affiliated with National Diagnostic Imaging (NDI) for its MRI interpretations. Medical Care will bill for the technical component for scans performed during its leased time on the unit.

Services and Equipment

Sycamore Shoals Hospital has acquired a new MRI unit, Toshiba Titan 1.5, 16 channel, short bore (the "Toshiba MRI"), to replace its General Electric 1.5T Signa, 4-channel, short bore. The Toshiba MRI is expected to be installed and operational by June 1, 2015. In the event that the Agency grants the CON Application but the Toshiba is not operational yet, Sycamore Shoals Hospital will make available to Medical Care for use a mobile MRI unit (the "Mobile MRI"), if necessary, so that the Practice may provide MRI services to its patients prior to the Toshiba becoming operational. Services to be provided are MRI scans of the Abdomen, Brain, Chest, Extremities, Neck, Pelvis, and Spine.

Ownership Structure

The MRI service will be operated as an ancillary service of the clinical practice of Medical Care. During the time Medical Care utilizes the MRI pursuant to the lease, it will be limited to the use of Medical Care physicians' patients.

Service Area

In 2014, Medical Care saw a total of 23,275 patients. 11,716 (50.33%) of the patients resided in Carter County. 8,130 (34.93%) of the patients resided in Washington County. 1,110 (4.77%) of the patients resided in Sullivan County. 871 (3.74%) of the patients resided in Johnson County. 608 (2.6%) of the patients resided in Unicoi County. No other counties in Tennessee accounted for greater than 2% of Medical Care's patient base. Accordingly, the service area for the MRI service is comprised of Carter, Johnson, Sullivan, Unicoi and Washington counties. With the exception of Sullivan County, all of the counties comprising the Applicant's service area -- Carter, Johnson, Unicoi and Washington -- are designated as medically underserved areas ("MUA") by the United States Health Resources and Services Administration.

Need

Medical Care physicians had a total of 75,049 patient encounters during 2014. With both primary care physicians and medical specialists seeing patients, the need for MRI scans often arises. During the year 2014, Medical Care physicians referred a total of 692 patients for MRI scans.

The shared equipment arrangement with Sycamore Shoals Hospital will enable the physicians of the Practice to provide seamless continuity of care and better manage their patients' course of care. The arrangement also represents the best and most efficient use of health care resources. The Sycamore Shoals unit has sufficient unused capacity to accommodate the Practice's patients, and the proposed sharing arrangement is a superior alternative to bringing another full time unit into the market.

Existing Resources

Comprehensive utilization data for the years 2011-2013 for all MRI units operating in the proposed service area is attached as Attachment C, I, Need a.1.a.There are 21 fixed MRI units and 1 mobile MRI unit in the proposed service area, operated by 16 providers. Two (2) of the 21 fixed MRI units are "specialty MRI units" and perform only scans of extremities[4]. The MRI utilization of all of the 21 fixed MRI units in the proposed service area was 47,064 procedures in 2013 (for an average utilization of 2241) and 49676 procedures in 2012 (for an average utilization of 2366). Excluding the two extremity-only scanners, the MRI utilization of fixed MRI units in the proposed service area was 46662 procedures in 2013 (for an average utilization of 2456) and 49051 procedures in 2012 (for an average utilization of 2582).

Most of the fixed units in operation in the proposed service area operating below the 2,880 per unit utilization threshold are at private physician practices. Only two of the hospital units operating in the proposed service area are below the utilization threshold, namely, Unicoi County Memorial Hospital and Sycamore Shoals Hospital. Medical Care proposes to share the Sycamore Shoals Hospital unit, rather than bring an additional MRI into the market. This proposal will bring the MRI unit at Sycamore Shoals Hospital much closer to the utilization threshold and is the most efficient use of resources.

Project Cost and Funding

Because the MRI unit in question will already be in place and operational, the project costs in this application consist primarily of the cost of the space and equipment lease. There is no construction or renovation involved in this project. The project will be funded through operating revenues and cash reserves.

The lease payment for the use of the Hospital's facility space, equipment and personnel (excluding the personnel needed to register the Practice's patients, a diagnostic-imaging technician and physician personnel for professional interpretation or analysis) is due to be paid within fifteen (15) days following the end of each month as follows:

(i) Eight Hundred and Seventeen Dollars ($817.00) per each four (4) hours of Block Time during which the GE MRI and Mobile MRI are used by Medical Care.

(ii) One Thousand and Twenty Four Dollars ($1,024.00) per each four (4) hours of Block Time during which the New MRI Unit is used by PLLC.

(iii) Twenty Dollars and Eighty Three Cents ($20.83) per month for PLLC's use of two storage lockers at the Hospital.

The lease between the parties permits Medical Care to use Sycamore Shoals Hospital's premises and equipment in three (3) "block times" of 4 hours each (on Tuesdays from 7:00am until 11:00am and from 11:30 until 3:30pm and on Fridays from 7:00am until 11:00am), for a total of twelve (12) hours each week. Each year the parties may mutually agree to adjust the "block times."

Under this arrangement, Medical Care anticipates that the cost associated with its use of the premises and equipment will be $159,744 annually ($3,072 per week for 3 blocks x 52 weeks) and

[4] Both units are owned by Appalachian Orthopedic Associates. One is located in Johnson City in Washington County. The other is located in Sullivan County.

that the cost associated with its use of lockers will be $249.96 annually ($20.83/month x 12 months), signifying a total annual lease cost of $159.993.96. The initial term of the lease is 10 years, so the total of the lease payments is $1,599,939.60.

Financial Feasibility

As reflected on the Projected Data Chart, the project produces a positive net operating income in the first two years of operation. No capital cost is required, and the project has a positive cash flow from the outset.

Staffing

Minimal additional staffing by Medical Care is required by this project. The Practice has one existing full-time MRI technician who will work 12 hours per week at the hospital (3 x 4hr blocks plus 30 minutes prior and after each block) and the remainder of his/her hours during the week doing other radiology procedures at the Practice. Medical Care anticipates using the existing full-time receptionist at Sycamore Shoals Hospital (at a rate of $13.75 per hour x 12 hours per week) to register patients during each block time. Radiological interpretations will be provided and billed by National Diagnostic Imaging (NDI).

II. Provide a detailed narrative of the project by addressing the following items as they relate to the proposal.

A. Describe the construction, modification and/or renovation of the facility (exclusive of major medical equipment covered by T.C.A. § 68-11-1601 et seq.) including square footage, major operational areas, room configuration, etc. Applicants with hospital projects (construction cost in excess of $5 million) and other facility projects (construction cost in excess of $2 million) should complete the Square Footage and Cost per Square Footage Chart. Utilizing the attached Chart, applicants with hospital projects should complete Parts A.-E. by identifying as applicable nursing units, ancillary areas, and support areas affected by this project. Provide the location of the unit/service within the existing facility along with current square footage, where, if any, the unit/service will relocate temporarily during construction and renovation, and then the location of the unit/service with proposed square footage. The total cost per square foot should provide a breakout between new construction and renovation cost per square foot. Other facility projects need only complete Parts B.-E. Please also discuss and justify the cost per square foot for this project.

If the project involves none of the above, describe the development of the proposal.

No construction, modification or renovation of a facility or hospital is involved in this project. Rather, the Applicant intends to lease (on a part-time basis) an existing MRI unit located at an existing hospital facility, namely, Sycamore Shoals Hospital.

B. Identify the number and type of beds increased, decreased, converted, relocated, designated, and/or redistributed by this application. Describe the reasons for change in bed allocations and describe the impact the bed change will have on the existing services.

N/A.

SQUARE FOOTAGE AND COST PER SQUARE FOOTAGE CHART N/A.

A. Unit / Department	Existing Location	Existing SF	Temporary Location	Proposed Final Location	Proposed Final Square Footage			Proposed Final Cost/ SF	
					Renovated	New	Total	Renovated	New
B. Unit/Depart. GSF Sub-Total									
C. Mechanical/ Electrical GSF									
D. Circulation /Structure GSF									
E. Total GSF									

C. **As the applicant, describe your need to provide the following health care services (if applicable to this application):**

(13). Magnetic Resonance Imaging (MRI)

Medical Care is a multispecialty physician group consisting of 17 physicians and 14 physician extenders in specialties that include family practice, general practice, internal medicine, general surgery, gynecology and pediatrics with office locations in Elizabethton, Hampton and Johnson City, in Tennessee.

Medical Care physicians had a total of 75,049 patient encounters during 2014. With both primary care physicians and medical specialists seeing patients, the need for MRI scans often arises. During the year 2014, Medical Care physicians referred a total of 692 patients for MRI scans:

Type of MRI	Number of Patients
MRI-Abdomen	26
MRI-Brain	117
MRI-Chest	2
MRI-Extremity	31
MRI-Neck	106
MRI-Pelvis	8
MRI-Spine	402
TOTAL	692

The shared equipment arrangement with Sycamore Shoals Hospital will enable the physicians of the Practice to provide seamless continuity of care and better manage their patients' course of care. The arrangement also represents the best and most efficient use of health care resources. The Sycamore Shoals unit has sufficient unused capacity to accommodate the Practice's patients, and the proposed sharing arrangement is a superior alternative to bringing another full time unit into the market.

D. **Describe the need to change location or replace an existing facility.**

N/A.

E. **Describe the acquisition of any item of major medical equipment (as defined by the Agency Rules and the Statute) which exceeds a cost of $1.5 million; and/or is a magnetic resonance imaging (MRI) scanner, positron emission tomography (PET) scanner, extracorporeal lithotripter and/or linear accelerator by responding to the following:**

Medical Care will acquire on a part-time basis through a lease an existing MRI unit owned by Sycamore Shoals Hospital.

1. For fixed-site major medical equipment (not replacing existing equipment):

a. Describe the new equipment, including:

1. Total cost; (as defined by Agency Rule)

Medical Care anticipates that the cost associated with its lease of the premises and MRI equipment at Sycamore Shoals Hospital will be $159,744 annually ($3,072 per week for 3 blocks x 52 weeks) and that the cost associated with its use of lockers will be $249.96 annually ($20.83/month x 12 months), signifying a total annual lease cost of $159,993.96. The term of the lease is 10 years, so the total of the lease payments is $1,599,939.60.

2. Expected useful life;
15 Years

3. List of clinical applications to be provided; and

Please see the charge schedule attached as Attachment B, II, E, 3 for a list of the clinical (diagnostic) applications.

4. Documentation of FDA approval. A copy of the FDA approval letter is attached as Attachment B, II, E, 4.

b. Provide current and proposed schedules of operations.

The lease between the parties permits Medical Care to use Sycamore Shoals Hospital's premises and equipment in three (3) "block times" of 4 hours each (on Tuesdays from 7:00am until 11:00am and from 11:30 until 3:30pm and on Fridays from 7:00am until 11:00am), for a total of twelve (12) hours each week. Each year the parties may mutually agree to adjust the "block times."

2. For mobile major medical equipment:

N/A.

a. List all sites that will be served;

b. Provide current and/or proposed schedule of operations;

c. Provide the lease or contract cost.

d. Provide the fair market value of the equipment; and

e. List the owner for the equipment.

3. Indicate applicant's legal interest in equipment (*i.e.*, purchase, lease, etc.) In the case of equipment purchase include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments.

Medical Care plans to lease on a part-time basis an existing MRI unit owned by Sycamore Shoals Hospital. A copy of the lease agreement is attached as Attachment A, 6. Sycamore Shoals bore the cost of the equipment purchase.

III. (A) Attach a copy of the plot plan of the site on an 8 1/2" x 11" sheet of white paper which must include:

1. **Size of site (*in acres*);**
2. **Location of structure on the site; and**
3. **Location of the proposed construction.**
4. **Names of streets, roads or highway that cross or border the site.**

Please note that the drawings do not need to be drawn to scale. Plot plans are required for all projects.

A plot plan is attached as Attachment B, III.

(B) 1. Describe the relationship of the site to public transportation routes, if any, and to any highway or major road developments in the area. Describe the accessibility of the proposed site to patients/clients.

The MRI is located at Sycamore Shoals Hospital at 1501 West Elk Avenue in Elizabethton, Tennessee, which is across the street from Medical Care's medical offices at 1500 West Elk Avenue. West Elk Avenue is a 4-lane highway also known as Hwy 67 and Hwy 321 that is readily accessible to patients in or traveling to the Elizabethton area. West Elk Avenue is the busiest road in Carter County.

Elizabethton does not have a public transportation system. From Johnson City / Washington County, patients can travel on Hwy 67 (6-7miles) and see the office on the right. From Unicoi County, patients can travel Hwy 26 north to exit 24 right onto Hwy 67 and then find the hospital on the left. From Bristol / Sullivan County, patients can travel 19E south toward Elizabethton, turn right on Hwy 67, and see the hospital on the right. From Kingsport / Sullivan County, patients can travel Hwy 26 South to exit 24, turn left on Hwy 67, and find the hospital on the left.

IV. Attach a floor plan drawing for the facility which includes legible labeling of patient care rooms (noting private or semi-private), ancillary areas, equipment areas, etc. on an 8 1/2" x 11" sheet of white paper.

NOTE: *DO NOT SUBMIT BLUEPRINTS*. Simple line drawings should be submitted and need not be drawn to scale.

A floor plan is attached as Attachment B, IV.

V. For a Home Health Agency or Hospice, identify:

N/A.

1. **Existing service area by County;**
2. **Proposed service area by County;**
3. **A parent or primary service provider;**
4. **Existing branches; and**
5. **Proposed branches.**

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

In accordance with Tennessee Code Annotated § 68-11-1609(b), "no Certificate of Need shall be granted unless the action proposed in the application for such Certificate is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, and will contribute to the orderly development of health care." The three (3) criteria are further defined in Agency Rule 0720-4-.01. Further standards for guidance are provided in the state health plan (Guidelines for Growth), developed pursuant to Tennessee Code Annotated §68-11-1625.

The following questions are listed according to the three (3) criteria: (I) Need, (II) Economic Feasibility, and (III) Contribution to the Orderly Development of Health Care. Please respond to each question and provide underlying assumptions, data sources, and methodologies when appropriate. *Please type each question and its response on an 8 1/2" x 11" white paper*. All exhibits and tables must be attached to the end of the application in correct sequence identifying the question(s) to which they refer. If a question does not apply to your project, indicate "Not Applicable (NA)."

QUESTIONS

I. NEED

1. Describe the relationship of this proposal toward the implementation of the State Health Plan and Tennessee's Health: Guidelines for Growth.

Please discuss how the proposed project will relate to the 5 Principals for Achieving Better Health found in the State Health Plan." Please type out each principal and provide a separate response to each one.

1 The Purpose of the State Health Plan is to improve the Health of Tennesseans.

The proposed sharing arrangement will improve patient access to important diagnostic equipment and promote coordinated patient care, which will, in turn, improve patient health outcomes. Patients diagnosed sooner can receive faster treatment resulting in better outcomes at lower overall costs.

2 Every Citizen should have reasonable access to healthcare.

The proposed sharing arrangement with a facility located directly across the street from the Practice in Carter County will improve patient access to important diagnostic testing. If this Project is approved, wait times for patients of the Practice who need MRI scans will diminish given the Practice's access to the Sycamore Shoals Hospital MRI scanner during times that have been specifically reserved as a result of the sharing arrangement. The inconvenience faced by patients who had to travel miles from the Practice to access other MRI scanners that were available sooner for purposes of scheduling an MRI should be almost eliminated by the

proposed arrangement. Patients diagnosed sooner can receive faster treatment resulting in better outcomes at lower overall costs.

3 **The state's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies, and the continued development of the state's health care system.**

The proposed project promotes economic efficiencies because the costs associated with its implementation are substantially lower than those associated with the Practice's acquisition of its own MRI unit. Additionally, the proposed project contributes to the orderly development of the State's health care system by optimizing the utilization of an existing MRI unit and not duplicating services. Markets can remain competitive because the proposed project would not result in underutilization of existing providers.

4 **Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers; and**

Medical Care, PLLC is a NCQA[5] certified level 3 Patient Centered Medical Home[6]. In order to obtain this level of certification, the practice achieved the highest level of coordinated proactive patient centered care after being evaluated both onsite and offsite according to NCQA standards, known throughout the healthcare industry as being the most rigorous in evaluating quality of care.

Medical Care, PLLC is currently accredited by the American College of Radiology (ACR) for existing imaging modalities of CT and nuclear medicine. Once the new MRI is in place at Sycamore Shoals Hospital, the facility (and Medical Care) will begin the process to become accredited by ACR. This ACR accreditation should be completed within the first year of the MRI's operation and will signify that there are appropriate quality and safety standards in place and that there are qualified personnel operating the MRI and monitoring the MRI equipment specifications and performance so as to meet all state and federal requirements.

5 **The state should support the development, recruitment, and retention of a sufficient and quality health care workforce.**

If this project is approved, Medical Care, PLLC intends to work with National Diagnostic Imaging (NDI) for its MRI interpretations (NDI will use teleradiology via PACS technology in reviewing MRI scans). NDI radiologists are board certified, fellowship trained and licensed in Tennessee. Several have subspecialty in MRI and specifically in neuroradiology. The

[5] National Committee for Quality Assurance ("NCQA") is a private, 501(c)(3) not-for-profit organization which manages voluntary accreditation programs for individual physicians, health plans, and medical groups.

[6] Blue Cross Blue Shield (BCBS) of Tennessee is a formal sponsor of the NCQA Patient-Centered Medical Home ("PCMH") Recognition program. Level 3 designation by NCQA is the highest achievable recognition for a medical group. NCQA's Patient Centered Medical Home program recognizes physician practices that prioritize the strengthening of the physician-patient relationship, coordinate care for patients across multiple settings, and engage in a team approach to improving patient care.

radiologists meet continuing medical education requirements and maintain current Tennessee licenses.

NDI is located in Beachwood, Ohio. The company has been providing subspecialty teleradiology services to hospitals, imaging centers, office-based imaging practices and outpatient clinics nationwide since 2003.

a. **Please provide a response to each criterion and standard in Certificate of Need Categories that are applicable to the proposed project. Do not provide responses to General Criteria and Standards (pages 6-9) here.**

MAGNETIC RESONANCE IMAGING (MRI)

Standards and Criteria

1. **Utilization Standards for non-Specialty MRI Units.**

a. **An applicant proposing a new non-Specialty stationary MRI service should project a minimum of at least 2160 MRI procedures in the first year of service, building to a minimum of 2520 procedures per year by the second year of service, and building to a minimum of 2880 procedures per year by the third year of service and for every year thereafter.**

The 2880 HSDA threshold anticipates that facilities will operate at or above 80% of a total capacity of 3600 procedures. For stationary MRI units, 3600 total capacity assumes that 1.2 procedures are performed per hour x 12 hours per day x 5 days per week x 50 weeks per year.

Assuming 1.2 MRI procedures per hour as per the HSDA utilization threshold calculation, Medical Care's ideal capacity given its proposed part-time use of the MRI at Sycamore Shoals Hospital 12 hours per week (3 blocks of 4 hours each) would be 1.2 procedures performed per hour x 12 hours per week x 50 weeks per year, or 720 procedures annually. 80% of 720 calculates to 576 procedures.

During the year 2014, Medical Care physicians referred patients for a total of 692 MRI scans:

Type of MRI	Number of Patients
MRI-Abdomen	26
MRI-Brain	117
MRI-Chest	2
MRI-Extremity	31
MRI-Neck	106
MRI-Pelvis	8
MRI-Spine	402
TOTAL	692

Meeting 80% of a total 720 procedure threshold is not expected to be an issue for Medical Care.

Comprehensive utilization data for the years 2011-2013 for all MRI units operating in the proposed service area is attached as Attachment C, I, Need a.1.a. There are 21 fixed MRI units and 1 mobile MRI unit in the proposed service area, operated by 16 providers. Two (2) of the 21 fixed MRI units are "specialty MRI units" and perform only scans of extremities[7]. The MRI utilization of all of the 21 fixed MRI units in the proposed service area was 47,064 procedures in 2013 (for an average utilization of 2241) and 49676 procedures in 2012 (for an average utilization of 2366). Excluding the two extremity-only scanners, the MRI utilization of fixed MRI units in the proposed service area was 46662 procedures in 2013 (for an average utilization of 2456) and 49051 procedures in 2012 (for an average utilization of 2582).

Most of the fixed units in operation in the proposed service area that are operating below the 2,880 per unit utilization threshold are at private physician practices. Only two of the hospital units operating in the proposed service area are below the utilization threshold, namely, Unicoi County Memorial Hospital and Sycamore Shoals Hospital. Sycamore Shoals Hospital MRI utilization for 2013 was 1719, a difference in HSDA's utilization threshold of 1161.

The Sycamore Shoals unit has sufficient unused capacity to accommodate the Practice's patients, and the proposed sharing arrangement is a superior alternative to bringing another full time unit into the market. Further, Medical Care's proposed sharing of the Sycamore Shoals Hospital unit in lieu of a proposed purchase of its own unit will bring the MRI unit at Sycamore Shoals Hospital much closer to the utilization threshold and is the most efficient use of resources. Most importantly, the proposed sharing arrangement with Sycamore Shoals Hospital will enable the physicians of the Practice to provide seamless continuity of care and better manage their patients' course of care. The arrangement represents the best and most efficient use of health care resources.

Future MRI utilization

Medical Care, PLLC has grown consistently over the past 15+ years and anticipates continued annually growth of at least 5%. The MRI utilization should grow consistently with the group and patient volumes. Thus, Medical Care anticipates that its MRI studies for the 1st year of operation will be 726 and 762 in the 2nd year of operation.

b. Providers proposing a new non-Specialty mobile MRI service should project a minimum of at least 360 mobile MRI procedures in the first year of service per day of operation per week, building to an annual minimum of 420 procedures per day of operation per week by the second year of service, and building to a minimum of 480 procedures per day of operation per week by the third year of service and for every year thereafter.

Not applicable.

c. An exception to the standard number of procedures may occur as new or improved technology and equipment or new diagnostic applications for MRI units are developed. An applicant must demonstrate that the proposed unit offers a unique and necessary technology for the provision of health care services in the Service Area.

[7] Both units are owned by Appalachian Orthopedic Associates. One is located in Johnson City in Washington County. The other is located in Sullivan County.

Not applicable.

d. Mobile MRI units shall not be subject to the need standard in paragraph 1 b if fewer than 150 days of service per year are provided at a given location. However, the applicant must demonstrate that existing services in the applicant's Service Area are not adequate and/or that there are special circumstances that require these additional services.

Not applicable.

e. Hybrid MRI Units. The HSDA may evaluate a CON application for an MRI "hybrid" Unit (an MRI Unit that is combined/utilized with medical equipment such as a megavoltage radiation therapy unit or a positron emission tomography unit) based on the primary purposes of the Unit.

Not applicable.

2. Access to MRI Units. All applicants for any proposed new MRI Unit should document that the proposed location is accessible to approximately 75% of the Service Area's population. Applications that include non-Tennessee counties in their proposed Service Areas should provide evidence of the number of existing MRI units that service the non-Tennessee counties and the impact on MRI unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity (if that data are available).

The MRI scanner that Medical Care is proposing to share is located directly across the street from the building housing the Practice's Elizabethton office at Sycamore Shoals Hospital. In 2014, Medical Care saw a total of 23,275 patients. 11,716 (50.33%) of the patients resided in Carter County. 8,130 (34.93%) of the patients resided in Washington County. 1,110 (4.77%) of the patients resided in Sullivan County. 871 (3.74%) of the patients resided in Johnson County. 608 (2.6%) of the patients resided in Unicoi County. No other counties in Tennessee accounted for greater than 2% of Medical Care's patient base. Accordingly, the service area for the MRI service is comprised of Carter, Johnson, Sullivan, Unicoi and Washington counties. With the exception of Sullivan County, all of the counties comprising the Applicant's service area -- Carter, Johnson, Unicoi and Washington -- are designated as medically underserved areas ("MUA") by the United States Health Resources and Services Administration.

Given the experience of Medical Care, PLLC at the Elizabethton office, the proposed location of the MRI unit will prove accessible to at least 75% of the service area's population.

3. Economic Efficiencies. All applicants for any proposed new MRI Unit should document that alternate shared services and lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

In Carter County, Tennessee, where the MRI is located and where over 50% of the Practice's patients resided in 2014, there is currently only one (1) provider offering MRI services, namely, Sycamore Shoals Hospital. According to the most recent utilization data available, this hospital MRI unit operated below the 2,880 per unit utilization threshold in 2011, 2012 and 2013. Sycamore Shoals Hospital MRI utilization for 2013 was 1719, a difference in HSDA's utilization threshold of 1161.

The Sycamore Shoals unit has sufficient unused capacity to accommodate the Practice's patients, and the proposed sharing arrangement is a superior alternative to bringing another full time unit into the market. Further, Medical Care's proposed sharing of the Sycamore Shoals Hospital unit in lieu of a proposed purchase of its own unit will bring the MRI unit at Sycamore Shoals Hospital much closer to the utilization threshold and is the most efficient use of resources. Most importantly, the proposed sharing arrangement with Sycamore Shoals Hospital will enable the physicians of the Practice to provide seamless continuity of care and better manage their patients' course of care. The arrangement represents the best and most efficient use of health care resources.

4. Need Standard for non-Specialty MRI Units.

A need likely exists for one additional non-Specialty MRI unit in a Service Area when the combined average utilization of existing MRI service providers is at or above 80% of the total capacity of 3600 procedures, or 2880 procedures, during the most recent twelvemonth period reflected in the provider medical equipment report maintained by the HSDA. The total capacity per MRI unit is based upon the following formula:

> **Stationary MRI Units: 1.20 procedures per hour x twelve hours per day x 5 days per week x 50 weeks per year = 3,600 procedures per year**
>
> **Mobile MRI Units: Twelve (12) procedures per day x days per week in operation x 50 weeks per year. For each day of operation per week, the optimal efficiency is 480 procedures per year, or 80 percent of the total capacity of 600 procedures per year.**

The 2880 HSDA threshold anticipates that facilities will operate at or above 80% of a total capacity of 3600 procedures. For stationary MRI units, 3600 total capacity assumes that 1.2 procedures are performed per hour x 12 hours per day x 5 days per week x 50 weeks per year.

Assuming 1.2 MRI procedures per hour as per the HSDA utilization threshold calculation, Medical Care's ideal capacity given its proposed part-time use of the MRI at Sycamore Shoals Hospital 12 hours per week (3 blocks of 4 hours each) would be 1.2 procedures performed per hour x 12 hours per week x 50 weeks per year, or 720 procedures annually. 80% of 720 calculates to 576 procedures.

During the year 2014, Medical Care physicians referred patients for a total of 692 MRI scans:

Type of MRI	Number of Patients
MRI-Abdomen	26
MRI-Brain	117
MRI-Chest	2

MRI-Extremity	31
MRI-Neck	106
MRI-Pelvis	8
MRI-Spine	402
TOTAL	692

Meeting 80% of a total 720 procedure threshold is not expected to be an issue for Medical Care.

Comprehensive utilization data for the years 2011-2013 for all MRI units operating in the proposed service area is attached as Attachment C, I, Need a.1.a. There are 21 fixed MRI units and 1 mobile MRI unit in the proposed service area, operated by 16 providers. Two (2) of the 21 fixed MRI units are "specialty MRI units" and perform only scans of extremities[8]. The MRI utilization of all of the 21 fixed MRI units in the proposed service area was 47,064 procedures in 2013 (for an average utilization of 2241) and 49676 procedures in 2012 (for an average utilization of 2366). Excluding the two extremity-only scanners, the MRI utilization of fixed MRI units in the proposed service area was 46662 procedures in 2013 (for an average utilization of 2456) and 49051 procedures in 2012 (for an average utilization of 2582).

Most of the fixed units in operation in the proposed service area operating below the 2,880 per unit utilization threshold are at private physician practices. Only two of the hospital units operating in the proposed service area are below the utilization threshold, namely, Unicoi County Memorial Hospital and Sycamore Shoals Hospital. Medical Care proposes to share the Sycamore Shoals Hospital unit, which is located in Carter County where over 50% of the Practice's patients reside, rather than bring an additional MRI into the market. Sycamore Shoals Hospital is the sole provider offering MRI services in Carter County.

According to the most recent utilization data available, the Sycamore Shoals Hospital MRI unit operated below the 2,880 per unit utilization threshold in 2011, 2012 and 2013. Sycamore Shoals Hospital MRI utilization for 2013 was 1719, a difference in HSDA's utilization threshold of 1161.

The Sycamore Shoals unit has sufficient unused capacity to accommodate the Practice's patients, and the proposed sharing arrangement is a superior alternative to bringing another full time unit into the market. Further, Medical Care's proposed sharing of the Sycamore Shoals Hospital unit in lieu of a proposed purchase of its own unit will bring the MRI unit at Sycamore Shoals Hospital much closer to the utilization threshold and is the most efficient use of resources. Most importantly, the proposed sharing arrangement with Sycamore Shoals Hospital will enable the physicians of the Practice to provide seamless continuity of care and better manage their patients' course of care. The arrangement represents the best and most efficient use of health care resources.

5. Need Standards for Specialty MRI Units.

a. Dedicated fixed or mobile Breast MRI Unit. An applicant proposing to acquire a dedicated fixed or mobile breast MRI unit shall not receive a CON to use the MRI unit for non-dedicated purposes and shall demonstrate that annual utilization of the proposed MRI unit in the third year of operation is projected to be at least 1,600 MRI procedures (.80 times the total

[8] Both units are owned by Appalachian Orthopedic Associates. One is located in Johnson City in Washington County. The other is located in Sullivan County.

capacity of 1 procedure per hour times 40 hours per week times 50 weeks per year), and that:

1. **It has an existing and ongoing working relationship with a breast-imaging radiologist or radiology proactive group that has experience interpreting breast images provided by mammography, ultrasound, and MRI unit equipment, and that is trained to interpret images produced by an MRI unit configured exclusively for mammographic studies;** Not applicable

2. **Its existing mammography equipment, breast ultrasound equipment, and the proposed dedicated breast MRI unit are in compliance with the federal Mammography Quality Standards Act;** Not applicable

3. **It is part of or has a formal affiliation with an existing healthcare system that provides comprehensive cancer care, including radiation oncology, medical oncology, surgical oncology and an established breast cancer treatment program that is based in the proposed service area.** Not applicable

4. **It has an existing relationship with an established collaborative team for the treatment of breast cancer that includes radiologists, pathologists, radiation oncologists, hematologist/oncologists, surgeons, obstetricians/gynecologists, and primary care providers.** Not applicable

b. **Dedicated fixed or mobile Extremity MRI Unit. An applicant proposing to institute a Dedicated fixed or mobile Extremity MRI Unit shall provide documentation of the total capacity of the proposed MRI Unit based on the number of days of operation each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of the unit is capable of performing each hour. The applicant shall then demonstrate that annual utilization of the proposed MRI Unit in the third year of operation is reasonably projected to be at least 80 per cent of the total capacity. Non-specialty MRI procedures shall not be performed on a Dedicated fixed or mobile Extremity MRI Unit and a CON granted for this use should so state on its face.**
Not applicable

c. **Dedicated fixed or mobile Multi-position MRI Unit. An applicant proposing to institute a Dedicated fixed or mobile Multi-position MRI Unit shall provide documentation of the total capacity of the proposed MRI Unit based on the number of days of operation each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of MRI procedures the unit is capable of performing each hour. The applicant shall then demonstrate that annual utilization of the proposed MRI Unit in the third year of operation is reasonably projected to be at least 80 per cent of the total capacity. Non-specialty MRI procedures shall not be performed on a Dedicated fixed or mobile Multi-position MRI Unit and a CON granted for this use should so state on its face.** Not applicable

6. **Separate Inventories for Specialty MRI Units and non-Specialty MRI Units. If data availability permits, Breast, Extremity, and Multi-position MRI Units shall not be counted in the inventory of non-Specialty fixed or mobile MRI Units, and an inventory for each category of**

Specialty MRI Unit shall be counted and maintained separately. None of the Specialty MRI Units may be replaced with non-Specialty MRI fixed or mobile MRI Units and a Certificate of Need granted for any of these Specialty MRI Units shall have included on its face a statement to that effect. A non-Specialty fixed or mobile MRI Unit for which a CON is granted for Specialty MRI Unit purpose use-only shall be counted in the specific Specialty MRI Unit inventory and shall also have stated on the face of its Certificate of Need that it may not be used for non-Specialty MRI purposes. Noted.

7. Patient Safety and Quality of Care. **The applicant shall provide evidence that any proposed MRI Unit is safe and effective for its proposed use.**

a. The United States Food and Drug Administration (FDA) must certify the proposed MRI Unit for clinical use.

See Attachment B.II.E.1.a.4. The proposed MRI Unit has been approved for use by the FDA.

b. The applicant should demonstrate that the proposed MRI Procedures will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

Appropriate location of the magnet, installation of proper safety mechanisms, and documentation, training and implementation of all appropriate safety policies and procedures applicable in federal standards, manufacturer's specifications and licensing agencies will be established and enforced.

c. The applicant should demonstrate how emergencies within the MRI Unit facility will be managed in conformity with accepted medical practice.

The Applicant will adhere to the ACR Guidance Document for Safe MR Practices published by the American College of Radiology included in Attachment C.1.a.MRI Standards and Criteria 7.c. A physician will be on premises (in the hospital ER) and technician(s) appropriately trained in emergency response procedures will be present when patients are being scanned. A crash cart stocked with appropriate equipment and medications will be maintained at all times.

d. The applicant should establish protocols that assure that all MRI Procedures performed are medically necessary and will not unnecessarily duplicate other services.

The Applicant will adhere to the ACR Practice Guideline For Performing And Interpreting Magnetic Resonance Imaging (MRI) included in Attachment C.1.a.MRI Standards and Criteria 7.d.

e. An applicant proposing to acquire any MRI Unit or institute any MRI service, including Dedicated Breast and Extremity MRI Units, shall demonstrate that it meets or is prepared to meet the staffing recommendations and requirements set forth by the American College of Radiology, including staff education and training programs.

The Applicant is prepared to meet the staffing recommendations and requirements set forth by the American College of Radiology, including staff education and training programs.

f. All applicants shall commit to obtain accreditation from the Joint Commission, the American College of Radiology, or a comparable accreditation authority for MRI within two years following operation of the proposed MRI Unit.

Medical Care, PLLC will begin the process to become ACR accredited immediately following approval of the CON application. This ACR accreditation should be completed within the first year of operation.

g. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.

Medical Care, PLLC will use IPC, a local hospitalist group which specializes in in-patient care, for any necessary hospital admissions. Like Medical Care, PLLC, IPC participates in One Partner, the local health information exchange (HIE) along with Qualuable, a Medicare approved ACO / MSSP. Both of these increase patient coordination and efficiency and quality. IPC maintains privileges and access to all area hospitals in the Mountain States Health Alliance (MSHA) system as well as Wellmont facilities and will cover the Applicant's patients as needed[9]. Please see the letter from IPC included as Attachment C.1.a. MRI Standards and Criteria 7.g.

h. The applicant must provide supervision and interpretation by a board certified radiologist or physician demonstrating experience and training in the relevant imaging procedure, with certification by the appropriate regulatory body

If this project is approved, Medical Care, PLLC intends to work with National Diagnostic Imaging (NDI) for its MRI interpretations (NDI will use teleradiology via PACS technology in reviewing MRI scans). NDI radiologists are board certified, fellowship trained and licensed in Tennessee. Several have subspecialty in MRI and specifically in neuroradiology. The radiologists meet continuing medical education requirements and maintain current Tennessee licenses.

NDI is located in Beachwood, Ohio. The company has been providing subspecialty teleradiology services to hospitals, imaging centers, office-based imaging practices and outpatient clinics nationwide since 2003.

8. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

[9] IPC is not contracted with all hospitals in the proposed service area – it does not admit to Indian Path Medical Center, but does admit to Holston Valley, both within Kingsport.

If approved, Medical Care, PLLC will submit all data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

9. In light of Rule 0720-11.01, which lists the factors concerning need on which an application may be evaluated, and Principle No.2 in the State Health Plan, "Every citizen should have reasonable access to health care," the HSDA may decide to give special consideration to an applicant:

a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration?

With the exception of Sullivan County, all of the counties comprising the Applicant's service area -- Carter, Johnson, Unicoi and Washington -- are designated as medically underserved areas ("MUA") by the United States Health Resources and Services Administration. (In Johnson, Carter and Unicoi counties, the entire county is designated as a MUA. In Washington County, only the Bethesda Division Service Area is deemed an MUA).

b. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program; or

Not applicable.

c. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program; or

The Applicant is the largest TennCare provider in Carter County and already contracts with all TennCare MCOs. The Applicant also participates in the Medicare program. In 2014, 36.4% of the patients treated at Medical Care, PLLC were TennCare enrollees and 28.89% of the patients were on Medicare. (Medical Care, PLLC is one of the four principle primary care physician groups in Qualuable Medical Professionals, LLC, a Medicare Accountable Care Organization (ACO) which is a participant in the Medicare shared savings program).

d. Who is proposing to use the MRI unit for patients that typically require longer preparation and scanning times (e.g., pediatric, special needs, sedated, and contrast agent use patients). The applicant shall provide in its application information supporting the additional time required per scan and the impact on the need standard.

Medical Care, PLLC is a multi-specialty medical practice with 17 physicians and 14 physician extenders in specialties that include family practice, general practice, internal medicine, general surgery, gynecology and pediatrics. Elderly and pediatric patients account for approximately one-third (1/3) of all patients at Medical Care, PLLC (19%

of patients are over 60 years old; 12% of patients are less than 10 years old). As one of the largest TennCare providers, the practice also sees many mentally and physically disabled children in State custody. Further, the practice cares for the brain injured residents of Crumley House and adults with intellectual and developmental disabilities at Dawn of Hope and Envision. All of these patients do typically require longer preparation and scanning times, however, the practice does not anticipate that care of these patients will negatively affect its ability to meet its an appropriate utilization level[10] for MRI scans.

[END OF RESPONSES TO MRI CRITERIA AND STANDARDS]

2. Describe the relationship of this project to the applicant facility's long-range development plans, if any.

The project is consistent with the long-range plans of the Applicant as it will enable the physicians at Medical Care, PLLC to provide more comprehensive care to their patients in a more cost effective manner and increase patient access and convenience. Medical Care, PLLC has always focused on patient centered care. Medical Care's motto is "Medical care with a heart" which also ties into the company's heart logo. Medical Care was the first walk-in physician office in Carter County and is open on evenings and weekends. Medical Care has always focused on the highest quality while maintaining cost competiveness. As medical Care has grown, it has continued to add additional services and become comprehensive in ancillary services which also add to patient convenience and access. The practice implemented its current electronic medical records (EMR) system in 1997 and was one of the first adopters of this technology in Tennessee. The practice has continued to adopt technologies which aid in coordination with other physicians through its past partnership in CareSpark and its current participation with One Partner, the local health information exchange (HIE). MRI is the next logical addition in this long term plan to provide high quality, comprehensive services which are accessible and convenient to all patients. Having MRI will also improve patient coordination of imaging services and decrease treatment times. MRI will also allow Medical Care to control costs as we continue to transition from a current fee for service (quantity) reimbursement to a quality based reimbursement models.

Medical Care, PLLC is one of the four principle primary care physician groups in Qualuable Medical Professionals, LLC, a Medicare Accountable Care Organization (ACO) which is a participant in the Medicare shared savings program. Qualuable Medical Professionals has a triple aim to reform healthcare, namely, to improve service, to improve quality, and to lower costs. The ability to offer MRI services to its patients at such a proximate location to the practice (across the street) and to be able to control the scheduling of the MRI procedures will further all three of these goals by resulting in comprehensive coordinated results, control of patient quality of care and service and control over cost.

[10] Medical Care describes what it proposes is an appropriate utilization level for its MRI scans on page 16 of this Application in its response to Utilization Standards for non-Specialty MRI Units.

3. Identify the proposed service area and justify the reasonableness of that proposed area. Submit a county level map including the State of Tennessee clearly marked to reflect the service area. Please submit the map on 81/2" x 11" sheet white paper marked only with ink detectable by a standard photocopier (i.e., no highlighters, pencils, etc.).

In 2014, Medical Care saw a total of 23,275 patients. 11,716 (50.33%) of the patients resided in Carter County. 8,130 (34.93%) of the patients resided in Washington County. 1,110 (4.77%) of the patients resided in Sullivan County. 871 (3.74%) of the patients resided in Johnson County. 608 (2.6%) of the patients resided in Unicoi County. No other counties in Tennessee accounted for greater than 2% of Medical Care's patient base. Accordingly, the service area for the MRI service is comprised of Carter, Johnson, Sullivan, Unicoi and Washington counties. With the exception of Sullivan County, all of the counties comprising the Applicant's service area -- Carter, Johnson, Unicoi and Washington -- are designated as medically underserved areas ("MUA") by the United States Health Resources and Services Administration.

A county level map of the State of Tennessee marked to reflect the service area is included as Attachment C.Need.3.

4. A. Describe the demographics of the population to be served by this proposal.

The Applicant's proposed service area is comprised of Carter, Johnson, Unicoi, Sullivan and Washington counties in Tennessee. The area is home to roughly 385,961 people, with 57,359 in Carter County, 18,090 in Johnson County, 18,419 in Unicoi, 159,494 in Sullivan, and 132,599 in Washington County in 2015. The table below summarizes this Year 2015 projected population data available from the TN Department of Health as well as projected enrollee data available from the Bureau of TennCare, and demographic information from the US Census Bureau and the TN Department of Health for each county in the proposed service area:

Variable	*Carter*	*Johnson*	*Unicoi*	*Sullivan*	*Washington*	*Service Area*	*Tennessee*
Total Population in 2015	57,359	18,090	18,419	159,494	132,599	385,961	6,649,438
# of Females	29,296	8,382	9,399	82,312	67,713	197,102	3,403,267
% Female	51.07%	46.33%	51.03%	51.61%	51.07%	51.07%	51.18%
Age 65+	11,279	3,822	4,029	34,287	22,369	75,786	1,012,937
Age 65+, % Total Population	19.66%	21.13%	21.87%	21.5%	16.87%	19.64%	15.23%
TennCare Enrollees[11]	12,298	4,233	3,817	30,453	21,634	72,435	1,324,208
Females	7,069	2,343	2,181	17,439	12,585	41,617	766,798
TennCare Enrollees as a % of Total Population	21.44%	23.40%	20.72%	19.09%	16.32%	18.77%	19.91%
Median Age	42.8	43.7	44.9	44.0	39.6	43	35.9
Median Household Income	$31,842	$29,609	$32,292	$39,479	$42,075	$35,059	$44,298
Population % Below Poverty Level	22.9%	26.4%	21.7%	18.3%	18.3%	21.52%	17.6%

[11] TennCare enrollment data as of midmonth November 2014.

B. Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, and low-income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.

Medical Care, PLLC's participation in the TennCare and Medicare programs helps serve the special needs of the service area population, which, as indicated above in the response to 4.A., shows large female and elderly populations, low median household income and higher TennCare enrollment rates compared to Tennessee as a whole. Approval of this project will improve the population's access to diagnostic tests that can improve patient outcomes in both surgical and non surgical cases.

5. Describe the existing or certified services, including approved but unimplemented CONs, of similar institutions in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. Be certain to list each institution and its utilization and/or occupancy individually. Inpatient bed projects must include the following data: admissions or discharges, patient days, and occupancy. Other projects should use the most appropriate measures, e.g., cases, procedures, visits, admissions, etc.

There are no approved but unimplemented CONs of similar projects in the service area.

Comprehensive utilization data for the years 2011-2013 for all MRI units operating in the proposed service area is attached as Attachment C, I, Need a.1.a.[12].

There are 21 fixed MRI units and 1 mobile MRI unit in the proposed service area, operated by 16 providers. Two (2) of the 21 fixed MRI units are "specialty MRI units" and perform only scans of extremities[13]. The MRI utilization of all of the 21 fixed MRI units in the proposed service area was 47,064 procedures in 2013 (for an average utilization of 2241) and 49676 procedures in 2012 (for an average utilization of 2366). Excluding the two extremity-only scanners, the MRI utilization of fixed MRI units in the proposed service area was 46662 procedures in 2013 (for an average utilization of 2456) and 49051 procedures in 2012 (for an average utilization of 2582).

Most of the fixed units in operation in the proposed service area that are operating below the 2,880 per unit utilization threshold are at private physician practices. Only two of the hospital units operating in the proposed service area are below the utilization threshold, namely, Unicoi County Memorial Hospital and Sycamore Shoals Hospital. Sycamore Shoals Hospital MRI utilization for 2013 was 1719, a difference in HSDA's utilization threshold of 1161.

The Sycamore Shoals unit has sufficient unused capacity to accommodate the Practice's patients, and the proposed sharing arrangement is a superior alternative to bringing another full time unit into the market. Further, Medical Care's proposed sharing of the Sycamore Shoals Hospital unit in lieu of a proposed purchase of its own unit will bring the MRI unit at Sycamore Shoals Hospital much closer to the utilization threshold and is the most efficient use of resources. Most importantly, the proposed sharing arrangement with Sycamore Shoals Hospital will enable the

[12] The most current utilization data available through the State's equipment registry is as of 8/11/2014.

[13] Both units are owned by Appalachian Orthopedic Associates. One is located in Johnson City in Washington County. The other is located in Sullivan County.

physicians of the Practice to provide seamless continuity of care and better manage their patients' course of care. The arrangement represents the best and most efficient use of health care resources.

6. Provide applicable utilization and/or occupancy statistics for your institution for each of the past three (3) years and the projected annual utilization for each of the two (2) years following completion of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology must include detailed calculations or documentation from referral sources, and identification of all assumptions.

This is a proposed new service for Medical Care, PLLC. Accordingly, there is no historical data available.

During the year 2014, Medical Care physicians referred patients for a total of 692 MRI scans:

Type of MRI	Number of Patients
MRI-Abdomen	26
MRI-Brain	117
MRI-Chest	2
MRI-Extremity	31
MRI-Neck	106
MRI-Pelvis	8
MRI-Spine	402
TOTAL	692

Assuming 1.2 MRI procedures per hour as per the HSDA utilization threshold calculation, Medical Care's ideal capacity given its proposed part-time use of the MRI at Sycamore Shoals Hospital 12 hours per week (3 blocks of 4 hours each) would be 1.2 procedures performed per hour x 12 hours per week x 50 weeks per year, or 720 procedures annually. 80% of 720 calculates to 576 procedures.

Medical Care, PLLC has grown consistently over the past 15+ years and anticipates continued annually growth of at least 5%. The MRI utilization should grow consistently with the group and patient volumes. Thus, Medical Care anticipates that its MRI studies for the 1st year of operation (2015) will be 726 and 762 in the 2nd year of operation. (Utilization for the second and third years of operation assume the ability to perform more than 1.2 procedures per hour and/or additional adjustment of the "block times" available to Medical Care, PLLC, which is permitted under its MRI License Agreement with Sycamore Shoals Hospital.

Economic Feasibility

1. Provide the cost of the project by completing the Project Costs Chart on the following page.

Justify the cost of the project.

- **All projects should have a project cost of at least $3,000 on Line F. (Minimum CON Filing Fee). CON filing fee should be calculated from Line D. (See Application Instructions for Filing Fee**

- **The cost of any lease (building, land, and/or equipment) should be based on fair market value or the total amount of the lease payments over the initial term of the lease, whichever is greater. Note: This applies to all equipment leases including by procedure or "per click" arrangements. The methodology used to determine the total lease cost for a "per click" arrangement must include, at a minimum, the projected procedures, the "per click" rate and the term of the lease.**

- **The cost for fixed and moveable equipment includes, but is not necessarily limited to, maintenance agreements covering the expected useful life of the equipment; federal, state, and local taxes and other government assessments; and installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding, which should be included under construction costs or incorporated in a facility lease.**

- **For projects that include new construction, modification, and/or renovation; documentation must be provided from a contractor and/or architect that support the estimated construction costs.**

Projected costs are set forth on the Project Cost Chart included as Attachment C Economic Feasibility 1. Because the MRI unit in question will already be in place and operational, the project costs in this application consist primarily of the cost of the space and equipment lease. There is no construction or renovation involved in this project. The project will be funded through operating revenues and cash reserves.

The lease payment for the use of the Hospital's facility space, equipment and personnel (excluding the personnel needed to register the Practice's patients, a diagnostic-imaging technician and physician personnel for professional interpretation or analysis) is due to be paid within fifteen (15) days following the end of each month as follows:

(i) Eight Hundred and Seventeen Dollars ($817.00) per each four (4) hours of Block Time during which the GE MRI and Mobile MRI are used by Medical Care.

(ii) One Thousand and Twenty Four Dollars ($1,024.00) per each four (4) hours of Block Time during which the New MRI Unit is used by PLLC.

(iii) Twenty Dollars and Eighty Three Cents ($20.83) per month for PLLC's use of two storage lockers at the Hospital.

The lease between the parties permits Medical Care to use Sycamore Shoals Hospital's premises and equipment in three (3) "block times" of 4 hours each (on Tuesdays from 7:00am until 11:00am and from 11:30 until 3:30pm and on Fridays from 7:00am until 11:00am), for a total of twelve (12) hours each week. Each year the parties may mutually agree to adjust the "block times."

Under this arrangement, Medical Care anticipates that the cost associated with its use of the premises and equipment will be $159,744 annually ($3,072 per week for 3 blocks x 52 weeks) and that the cost associated with its use of lockers will be $249.96 annually ($20.83/month x 12 months), signifying a total annual lease cost of $159.993.96. The initial term of the lease is 10 years, so the total of the lease payments is $1,599,939.60.

2. **Identify the funding sources for this project.**

Please check the applicable item(s) below and briefly summarize how the project will be financed. (Documentation for the type of funding MUST be inserted at the end of the application, in correct alpha/numeric order and identified as Attachment C, Economic Feasibility-2.)

__ A. Commercial loan--Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;
__ B. Tax-exempt bonds--Copy of preliminary resolution or a letter from the issuing authority stating favorable initial contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;
__ C. General Obligation bonds—Copy of resolution from issuing authority or minutes from the appropriate meeting.
__ D. Grants--Notification of intent form for grant application or notice of grant award; or
X **E. Cash Reserves--Appropriate documentation from Chief Financial Officer.**
__ F. Other—Identify and document funding from all other sources.

3. Discuss and document the reasonableness of the proposed project costs. If applicable, compare the cost per square foot of construction to similar projects recently approved by the Health Services and Development Agency.

Because the MRI unit in question will already be in place and operational, the project costs in this application consist primarily of the cost of the space and equipment lease. There are no associated site acquisition, construction or renovation costs involved. The project will be funded through operating revenues and cash reserves.

Medical Care anticipates that the cost associated with its use of the premises and equipment will be $159,744 annually ($3,072 per week for 3 blocks x 52 weeks) and that the cost associated with its use of lockers will be $249.96 annually ($20.83/month x 12 months), signifying a total annual lease cost of $159.993.96. The initial term of the lease is 10 years, so the total of the lease payments is $1,599,939.60.

As indicated on the attached Project Costs Chart, the total project cost for this proposal is $1,608,550.71 (reflective of legal fees, space and equipment lease and CON filing fee). Medical Care submits that the costs are reasonable and justified in light of the costs of other similar applicants.

4. Complete Historical and Projected Data Charts on the following two pages--*Do not modify the Charts provided or submit Chart substitutions!* Historical Data Chart represents revenue and expense information for the last *three (3)* years for which complete data is available for the institution. Projected Data Chart requests information for the two (2) years following the completion of this proposal. Projected Data Chart should reflect revenue and expense projections for the *Proposal Only* (*i.e.*, if the application is for additional beds, include anticipated revenue from the proposed beds only, not from all beds in the facility).

The Historical Data Chart and the Projected Data Chart have been completed and are included as Attachment C Economic Feasibility 4.

5. Please identify the project's average gross charge, average deduction from operating revenue, and average net charge.

The project's average gross charge will be $1584.55 for MRI's. With the provision for contractual adjustments, charity and bad debt averaging $691.89 per scan, the average net charge then becomes $892.66.

6. **A. Please provide the current and proposed charge schedules for the proposal. Discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the proposed project and the impact on existing patient charges.**

As the proposal involves a new service (MRI), there are no current charge schedules and no projected adjustment to current charges. The average projected gross charge, average projected deduction (including projected contractual adjustments, provision for charity care and bad debts), the average projected net charge, and the anticipated revenue from the proposed project for the two years following completion are presented in the table below as well as in the Projected Data Chart.

	Year 1	Year 2
Average Gross Charge	$1584.55	$1584.55
Average Projected Deduction	$691.89	$691.89
Average Projected Net Charge	$892.66	$892.66
Anticipated Gross Operating Revenue	$1,150,383.30	$1,207,427.10
Anticipated Net Operating Revenue	$648,071.16	$680,207.00

B. Compare the proposed charges to those of similar facilities in the service area/adjoining service areas, or to proposed charges of projects recently approved by the Health Services and Development Agency. If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

A comparison of the proposed charges to the current Medicare allowable fee schedule by CPT code is represented in the table below:

CPT	MRI	Medical Care, PLLC Gross Charge	Medicare Physician Fee Schedule
70551	MRI HEAD W/O CONTRAST	$1,400.00	437.20
70552	MRI HEAD W/ CONTRAST	$1,640.00	488.23
70553	MRI HEAD W/ & W/O CONTRAST	$2,060.00	571.93
71550	MRI CHEST W/O CONTRAST	$1,400.00	477.68
71551	MRI CHEST W CONTRAST	$1,640.00	530.76
71552	MRI CHEST W & W/O CONTRAST	$2,200.00	675.02
72141	MRI CERVICAL SPINE W/O CONTRAST	$1,250.00	387.18
72142	MRI CERVICAL SPINE W/ CONTRAST	$1,500.00	498.10
72146	MRI THORACIC SPINE W/O CONTRAST	$1,400.00	387.86
72147	MRI THORACIC SPINE W/ CONTRAST	$1,500.00	439.92
72148	MRI LUMBAR SPINE W/O CONTRAST	$1,300.00	382.08
72149	MRI LUMBAR SPINE W/ CONTRAST	$1,600.00	481.43
72156	MRI C SPINE W/ & W/O CONTRAST	$2,000.00	572.27
72157	MRI T SPINE W/ & W/O CONTRAST	$2,000.00	531.78
72158	MRI L SPINE W/ & W/O CONTRAST	$2,000.00	560.02
72195	MRI PELVIS W/O CONTRAST	$1,250.00	432.09
72196	MRI PELVIS W CONTRAST	$1,500.00	480.06
72197	MRI PELVIS W & W/O CONTRAST	$1,900.00	585.88
73218	MRI UPPER EXTREMITY W/O CONTRAST	$1,200.00	424.95
73219	MRI UPPER EXTREMITY W CONTRAST	$1,450.00	471.56
73220	MRI UPPER EXTREMITY W & W/O CONTRAST	$1,750.00	581.45
73221	MRI UPPER EXTREMITY JOINT W/O CONTRAST	$1,200.00	282.05
73222	MRI UPPER EXTREMITY JOINT W CONTRAST	$1,400.00	442.64
73223	MRI UPPER EXTREMITY JOINT W & W/O CONTRAST	$1,900.00	548.11
73718	MRI LOWER EXTREMITY W/O CONTRAST	$1,200.00	422.23
73719	MRI LOWER EXTREMITY W CONTRAST	$1,400.00	479.38
73720	MRI LOWER EXTREMITY W & W/O CONTRAST	$1,750.00	585.20
73721	MRI LOWER EXTREMITY JOINT W/O CONTRAST	$1,200.00	282.05
73722	MRI LOWER EXTREMITY JOINT W CONTRAST	$1,350.00	449.10

73723	MRI LOWER EXTREMITY JOINT W & W/O CONTRAST	$1,950.00	547.77
74181	MRI ABDOMEN W/O CONTRAST	$1,400.00	382.42
74182	MRI ABDOMEN W CONTRAST	$1,600.00	528.04
74183	MRI ABDOMEN W & W/O CONTRAST	$2,000.00	587.92
MEDICAL CARE, PLLC AVERAGE GROSS CHARGE PER PROCEDURE		$1,584.55	

The Applicant's proposed average gross charge is reasonable in relation to those of similar facilities in the service area (average $2,850.07 in 2013) as demonstrated in the table below.

County	Facility	Average Gross Charge in 2013
Carter	Sycamore Shoals Hospital	$4,366.35
Johnson	Johnson County Community Hospital	$3,558.47
Sullivan	Appalachian Orthopedic Associates, PC	$1,063.90
Sullivan	Bristol Regional Medical Center	$2,751.47
Sullivan	Holston Valley Imaging Center, LLC	$2,682.13
Sullivan	Holston Valley Medical Center	$2,704.38
Sullivan	Indian Path Medical Center	$4,373.27
Sullivan	Meadowview Outpatient Diagnostic Center	$1,696.17
Sullivan	Sapling Grove Outpatient Diagnostic Center	$1,737.56
Sullivan	Volunteer Parkway Imaging Center	$2,661.13
Unicoi	Unicoi County Memorial Hospital	$2,299.97
Washington	Appalachian Orthopedic Associates –Johnson City	$1,063.11
Washington	Franklin Woods Community Hospital	$4,408.10
Washington	Johnson City Medical Center	$4,477.30
Washington	Mountain States Imaging at Med Tech Parkway	$4,307.68
Washington	Watauga Orthopedics, PLC	$1,450.18
AVERAGE GROSS CHARGE PER PROCEDURE		$2,850.07

7. Discuss how projected utilization rates will be sufficient to maintain cost-effectiveness.

Projected utilization is based on current utilization rates of MRI services of Medical Care, PLLC patients and the historic rate of growth in patients at the medical practice. The Projected Data Chart outlines the cost-effectiveness of the proposal. A positive cash flow is expected in the first year of operation.

8. Discuss how financial viability will be ensured within two years; and demonstrate the availability of sufficient cash flow until financial viability is achieved.

Revenue and expense information for this proposal for Years 1 and 2 following project completion is included in the Projected Data Chart. The net operating income less capital expenditures as represented is projected to be $386,107.24 in year 1 and $414,823.04 in year 2. As reflected on the Projected Data Chart, the project produces a positive net operating income in the first two years of operation. No capital cost is required, and the project has a positive cash flow from the outset.

9. Discuss the project's participation in state and federal revenue programs including a description of the extent to which Medicare, TennCare/Medicaid, and medically indigent patients will be served by the project. In addition, report the estimated dollar amount of revenue and percentage of total project revenue anticipated from each of TennCare, Medicare, or other state and federal sources for the proposal's first year of operation.

Medical Care, PLLC is the largest TennCare provider in Carter County and already contracts with all TennCare MCOs. The Practice also participates in the Medicare program. In 2014, 36.4% of the patients treated at Medical Care, PLLC were TennCare enrollees and 28.89% of the patients were on Medicare. (Medical Care, PLLC is one of the four principle primary care physician groups in Qualuable Medical Professionals, LLC, a Medicare Accountable Care Organization (ACO) which is a participant in the Medicare shared savings program). Private insurance accounted for 31.53% of the patients, Worker's Compensation accounted for 1% of the patients and private pay accounted for 2.5% of the patients. Medical Care, PLLC anticipates seeing a similar payor mix in the future.

The estimated dollar amount of revenue and percentage of total project revenue anticipated from TennCare and Medicare for the proposal's first year of operation is set forth below:

	TennCare	Medicare
Gross TennCare and Medicare MRI Revenues	$418,739.41	$ 332,460.77
% of Total MRI Revenues	36.4%	28.9%

10. Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For new projects, provide financial information for the corporation, partnership, or principal parties involved with the project. Copies must be inserted at the end of the application, in the correct alpha-numeric order and labeled as Attachment C, Economic Feasibility-10.

The most recent financial statements for Medical Care, PLLC and Pine Palms Management LLC (consolidated) are attached as requested and labeled Attachment C Economic Feasibility 10.

11. Describe all alternatives to this project which were considered and discuss the advantages and disadvantages of each alternative including but not limited to:

Options Considered by Medical Care, PLLC include:

Option One: Maintain the status quo/do nothing -- Medical Care, PLLC considered the option to do nothing and maintain the status quo, but this would result in continued patient delays in scheduling, large up-front fee deposits required prior to scheduling, and out of network issues for CIGNA patients. Doing nothing would also maintain the patient inconvenience factor as patients would still be likely to travel to out of county facilities for scans. Doing nothing will continue the lack of patient coordination and timely treatment.

Option Two: Obtaining approval to acquire a fixed MRI scanner for the Carter County location of the medical practice – Medical Care unsuccessfully applied to HSDA to exercise this option.

Option Three: Establishing a mobile MRI service -- this alternative is not optimal operationally or clinically and will not meet the current and growing patient care needs of Medical Care, PLLC. Initial cost evaluations are similar to those of a fixed magnet -- a mobile unit would require significant build-out costs for modifications to parking, weight support of trailer, electric supply, etc. Further, there is limited physical space for parking a mobile trailer close to the radiology area of the practice. Patients would be exposed to the elements (rain & snow etc.) in order to access the mobile unit. Handicapped patients would have to use a wheelchair lift to access the mobile unit rather than having ground level access to a fixed unit.

a. A discussion regarding the availability of less costly, more effective, and/or more efficient alternative methods of providing the benefits intended by the proposal. If development of such alternatives is not practicable, the applicant should justify why not; including reasons as to why they were rejected.

Medical Care, PLLC considered whether other less costly, more effective/efficient options existed. Medical Care, PLLC considered acquiring a lower cost extremities only MRI, but after reviewing the imaging needs of its patients, the practice concluded that the significant limitations associated with an extremities only MRI would not meet the needs of its patients and would also greatly reduce its utilization of an MRI which would decrease efficiency.

The practice also considered an open, low powered MRI. Medical Care determined that, while these systems can be less expensive initially, they have reduced quality images, particularly in neurologic studies and imaging larger patients. Since quality and patient care is our highest priority, this option was found insufficient to meet patients' needs.

Medical Care, PLLC considered establishing a mobile MRI service. This alterative would require significant modification to the parking lot and electrical service. Patients would be exposed to inclement weather (rain and snow), which would increase the risk of injury. Further, the mobile services which are housed in trailers can exacerbate symptoms for claustrophobic patients and prove less accessible for handicapped and injured patients. In reviewing pricing for mobile service, Medical Care, PLLC found that there was not a significant cost savings and the estimated patient load would require it to be parked permanently. After review, this option was eliminated due to several problems without any savings.

Medical Care, PLLC considered the option to do nothing and maintain the status quo, but this would result in continued patient delays in scheduling, large up-front fee deposits required prior to scheduling, and out of network issues for CIGNA patients. Doing nothing would also maintain the patient inconvenience factor as patients would still be likely to travel to out of county facilities for scans. Doing nothing will continue the lack of patient coordination and timely treatment.

b. The applicant should document that consideration has been given to alternatives to new construction, e.g., modernization or sharing arrangements. It should be documented that superior alternatives have been implemented to the maximum extent practicable.

This proposal IS a sharing arrangement and involves NO new construction.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

1. List all existing health care providers (e.g., hospitals, nursing homes, home care organizations, etc.), managed care organizations, alliances, and/or networks with which the applicant currently has or plans to have contractual and/or working relationships, e.g., transfer agreements, contractual agreements for health services.

Medical Care will continue to work closely with other healthcare providers in the area including: Mountain States Health Alliance hospitals, Wellmont Health Systems, East Tennessee State University, Lincoln Memorial University, local nursing homes, clinics and other healthcare providers, Medicare and all managed care plans in the area including Blue Cross Blue Shield, United Healthcare, Cigna, Crest Point, Highlands IPA, and Qualuable (ACO).

2. Describe the positive and/or negative effects of the proposal on the health care system. Please be sure to discuss any instances of duplication or competition arising from your proposal including a description of the effect the proposal will have on the utilization rates of existing providers in the service area of the project.

The proposal is beneficial to the health care system and will result in minimal to no negative effects from unnecessary duplication of services. Patients will benefit from the proposed sharing arrangement in many ways including, shorter wait times, improved convenience, expedited diagnosis and treatment and coordinated care.

3. Provide the current and/or anticipated staffing pattern for all employees providing patient care for the project. This can be reported using FTEs for these positions. Additionally, please compare the clinical staff salaries in the proposal to prevailing wage patterns in the service area as published by the Tennessee Department of Labor & Workforce Development and/or other documented sources.

Medical Care expects to use 1 existing full-time technician (who does other radiology procedures at the practice such as CT, x-ray and DeXA) as its MRI technician during its block times at the Hospital (12 hours per week plus 30 minutes before and after each of the 3 4-hour blocks). This technician's pay rate will be the same as it is currently ($24/hr plus benefits amounting to an additional $7.50/hr). The annual personnel cost associated with using this technician in connection with the proposed sharing arrangement is $24,570.00 ($31.50/hr x 15 hrs/week x 52 weeks/year).

According to the US Department of Labor, Bureau of Labor Statistics, as of May 2014, the hourly mean wage in Tennessee for radiologic technologists was $23.68 and the annual mean wage was

$49,250. The hourly rate Medical Care plans to pay its technician exceeds the hourly mean wage in Tennessee for radiologic technologists.

4. Discuss the availability of and accessibility to human resources required by the proposal, including adequate professional staff, as per the Department of Health, the Department of Mental Health and Developmental Disabilities, and/or the Division of Mental Retardation Services licensing requirements.

Medical Care, PLLC does not anticipate that finding appropriately licensed staff will be a problem as the practice receives many resumes of experienced technologists looking for work. Moreover, East Tennessee State University has a program training new 4 year technologists graduating each semester.

***5.* Verify that the applicant has reviewed and understands all licensing certification as required by the State of Tennessee for medical/clinical staff. These include, without limitation, regulations concerning physician supervision, credentialing, admission privileges, quality assurance policies and programs, utilization review policies and programs, record keeping, and staff education.**

The Applicant has reviewed and understands all licensing certification as required by the State of Tennessee for medical/clinical staff.

***6.* Discuss your health care institution's participation in the training of students in the areas of medicine, nursing, social work, etc. (*e.g.*, internships, residencies, etc.).**

Medical Care, PLLC works closely with East Tennessee State University in medical student rotations and nurse practitioners. The practice also works with King College and Milligan College in rotating and job shadowing nursing students.

7. (a) Please verify, as applicable, that the applicant has reviewed and understands the licensure requirements of the Department of Health, the Department of Mental Health and Developmental Disabilities, the Division of Mental Retardation Services, and/or any applicable Medicare requirements.

The Applicant has reviewed and understands the licensure requirements of the Department of Health and applicable Medicare requirements.

(b) Provide the name of the entity from which the applicant has received or will receive licensure, certification, and/or accreditation.

Accreditation: American College of Radiology

(c) If an existing institution, please describe the current standing with any licensing, certifying, or accrediting agency. Provide a copy of the current license of the facility.

Not applicable.

(d) For existing licensed providers, document that all deficiencies (if any) cited in the last licensure certification and inspection have been addressed through an approved plan of correction. Please include a copy of the most recent licensure/certification inspection with an approved plan of correction.

Not applicable.

8. Document and explain any final orders or judgments entered in any state or country by a licensing agency or court against professional licenses held by the applicant or any entities or persons with more than a 5% ownership interest in the applicant. Such information is to be provided for licenses regardless of whether such license is currently held.

No such final orders or judgments exist.

9. Identify and explain any final civil or criminal judgments for fraud or theft against any person or entity with more than a 5% ownership interest in the project.

No such final judgments exist.

10. If the proposal is approved, please discuss whether the applicant will provide the Tennessee Health Services and Development Agency and/or the reviewing agency information concerning the number of patients treated, the number and type of procedures performed, and other data as required.

If approved, Medical Care will submit all information required.

PROOF OF PUBLICATION

Attach the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit from the newspaper as proof of the publication of the letter of intent.

Attached as requested.

DEVELOPMENT SCHEDULE

1. Please complete the Project Completion Forecast Chart on the next page. If the project will be completed in multiple phases, please identify the anticipated completion date for each phase.

Completed as requested and attached as Project Completion Forecast Chart

2. If the response to the preceding question *indicates that the applicant does not anticipate completing the project within the period of validity as defined in the preceding paragraph,* please state below any request for an extended schedule and document the "good cause" for such an extension.

Not applicable.

Attachment A-3

FILED

COPY

Tennessee Articles of Organization of a Professional Limited Liability Company

This company is organized under the Tennessee Revised Limited Liability Company Act, more specifically, Tenn. Code Ann. §48-249-1101 et seq.

1. The name of the Professional Limited Liability Company is: Medical Care, PLLC.
2. The name and address of the Professional Limited Liability Company's initial registered office in Tennessee is: Rodney S. Klein, Esq., Klein & Associates, 110 Corporate Drive, Suite 150, Johnson City, TN in Washington County, Tennessee.
3. Number of members at the time of organization is 3.
4. The Professional Limited Liability Company will be member managed.
5. This document is to be effective as of the date of filing.
6. The complete address of the Professional Limited Liability Company's principal office is: 401 E. Main St., Johnson City, TN 37601 in Washington County.
7. The Period of Duration is perpetual.
8. The purpose of the Professional Limited Liability Company is to render medical services and other ancillary services.
9. The Professional Limited Liability Company has one or more qualified members and no disqualified members.

December 10, 2008
Signature Date

Jeffrey Hopland
Signature *(manager or member authorized to sign by the Professional Limited Liability Company)*

Member
Signer's Capacity

Jeffrey Hopland
Name

5410.0388

STATE OF TENNESSEE
Tre Hargett, Secretary of State
Division of Business Services
William R. Snodgrass Tower
312 Rosa L. Parks AVE, 6th FL
Nashville, TN 37243-1102

STEVEN HOPLAND
401 EAST MAIN STREET
JOHNSON CITY, TN 37601

April 23, 2015

Request Type: Certificate of Existence/Authorization
Request #: 0160462

Issuance Date: 04/23/2015
Copies Requested: 1

Document Receipt

Receipt # : 002023912	Filing Fee: $22.25
Payment-Credit Card - State Payment Center - CC #: 162207129	$22.25

Regarding: **MEDICAL CARE, PLLC**

Filing Type:	Limited Liability Company - Domestic	Control # :	592623
Formation/Qualification Date:	12/22/2008	Date Formed:	12/22/2008
Status:	Active	Formation Locale:	TENNESSEE
Duration Term:	Perpetual	Inactive Date:	
Business County:	CARTER COUNTY		

CERTIFICATE OF EXISTENCE

I, Tre Hargett, Secretary of State of the State of Tennessee, do hereby certify that effective as of the issuance date noted above

MEDICAL CARE, PLLC

* is a Limited Liability Company duly formed under the law of this State with a date of incorporation and duration as given above;

* has paid all fees, taxes and penalties owed to this State (as reflected in the records of the Secretary of State and the Department of Revenue) which affect the existence/authorization of the business;

* has filed the most recent annual report required with this office;

* has appointed a registered agent and registered office in this State;

* has not filed Articles of Dissolution or Articles of Termination. A decree of judicial dissolution has not been filed.

Tre Hargett
Secretary of State

Processed By: Cert Web User

Verification #: 011640616

OPERATING AGREEMENT
OF
MEDICAL CARE, PLLC

THIS AGREEMENT, made effective as of the 10th day of December, 2008, between ARNOLD HOPLAND, having an address at 104 Ridgecrest Dr., Elizabethton, TN 37643; JEFFREY HOPLAND having an address at 711 E. Holston Ave., Johnson City, TN 37601 and KENNETH HOPLAND having an address at 115 Stonebrook Loop, Elizabethton, TN 37643 (collectively hereinafter referred to as "Members").

WITNESSETH:

WHEREAS, the Members have formed a professional limited liability company pursuant to the laws of the State of Tennessee and the Members desire to establish their respective rights and obligations in connection with the limited liability company;

NOW, THEREFORE, in consideration of the mutual covenants set forth herein and other valuable consideration, the receipt and sufficiency of which hereby are acknowledged, the Members agree as follows:

1. Formation

The parties hereby confirm that the Members have formed a professional limited liability company (the "Limited Liability Company") pursuant to the provisions of the Tennessee Revised Limited Liability Company Act (Tenn. Code Ann. §48-249-101 et seq.) and more specifically the Tennessee Professional Revised Limited Liability Company Act (Tenn. Code Ann. Section 48-249-1101 et seq.), for the purposes and the period and upon the terms and conditions hereinafter set forth. The Articles of Organization of the Limited Liability Company has been filed and accepted by the State of Tennessee and the Members shall execute, acknowledge, swear to and file any other documents required under applicable law.

2. Name

The name of the Limited Liability Company shall be MEDICAL CARE, PLLC, and all business of the Limited Liability Company shall be conducted under said name, or such other name as the Members from time to time may determine.

3. Purposes

The purposes of the Limited Liability Company are to incur indebtedness, secured and unsecured; to enter into and perform contracts and agreements of any kind necessary to, in connection with or incidental to the business of the Limited Liability Company; and to carry on any other activities necessary to, in connection with or incidental to the foregoing, as the Members in their discretion may deem desirable. Additionally, the Limited Liability Company is and shall remain organized as a professional limited liability company under the laws of the State of Tennessee and as such shall as its primary purpose enter into the practice of medicine through its physician members. Members must be licensed physicians in the State of Tennessee and in good standing.

4. Place of Business

The principal place of business and specified office of the Limited Liability Company at which the records required to be maintained by the Limited Liability Company under the Tennessee Revised Limited Liability Company Act (Tenn. Code Ann. §48-249-101 et seq.) are to be kept shall be at 401 E. Main St., Johnson City, TN 37601, or at such other or additional places of business within or outside of the State of Tennessee as the Members from time to time may designate. The Members shall notify the other Members of any change of the principal place of business and specified office.

The Limited Liability Company hereby designates Rodney S. Klein, Esq. with an address at 110 Corporate Dr., Suite 150, Johnson City, TN 37604, as the Registered Agent of the Limited Liability Company for service of process.

The registered office and Registered Agent may be changed from time to time by the Members by filing the prescribed forms with the appropriate governmental authorities.

5. Term

The term of the Limited Liability Company shall commence on the filing of the Articles of Organization of the Limited Liability Company, and shall be perpetual unless the Limited Liability Company is sooner terminated in accordance with this Agreement.

6. Capital Contributions

Each of the Members shall contribute to the capital of the Limited Liability Company the amount set forth opposite his name below:

MEMBER	*CAPITAL CONTRIBUTION*
ARNOLD HOPLAND	$100.00
JEFFREY HOPLAND	$100.00
KENNETH HOPLAND	$100.00

The Members shall not be required to make any additional capital contributions.

Except as specifically provided in this Agreement or required by law, no Member shall have the right to withdraw or reduce his contributions to the capital of the Limited Liability Company until the termination of the Limited Liability Company. No Member shall have the right to demand and receive any distribution from the Limited Liability Company in any form other than cash, regardless of the nature of such Member's capital contribution. No Member shall be paid interest on capital contributions to the Limited Liability Company.

The liability of any Member for the losses, debts, liabilities and obligations of the Limited Liability Company shall be limited to paying: the capital contribution of such Member when due under this Agreement; such Member's share of any undistributed assets of the Limited Liability Company; and (only if and to the extent at any time required by applicable law) any amounts previously distributed to such Member by the Limited Liability Company.

7. Loans and Advances by Members

If any Member shall loan or advance any funds to the Limited Liability Company in excess of the capital contribution of such Member prescribed herein, such loan or advance shall not be deemed a capital contribution to the Limited Liability

Company and shall not in any respect increase such Member's interest in the Limited Liability Company.

8. Allocations and Distributions

As used in this Agreement, the terms "net profits" and "net losses" shall mean the profits or losses of the Limited Liability Company from the conduct of the Limited Liability Company's business, after all expenses incurred in connection therewith have been paid or provided for, including any allowance for depreciation or amortization of the cost of the realty.

The term "cash receipts" shall mean all cash receipts of the Limited Liability Company from whatever source derived, including without limitation capital contributions made by the Members; the proceeds of any sale, exchange, condemnation or other disposition of all or any part of the realty or other assets of the Limited Liability Company; the proceeds of any loan to the Limited Liability Company; the proceeds of any mortgage or refinancing of any mortgage on all or any part of the realty or other assets of the Limited Liability Company; the proceeds of any insurance policy for fire or other casualty damage payable to the Limited Liability Company; and the proceeds from the liquidation of the realty or other assets of the Limited Liability Company following a termination of the Limited Liability Company.

The term "capital transactions" shall mean any of the following: the sale of all or any part of the realty or other assets of the Limited Liability Company or interests therein; the refinancing or recasting of mortgages or other liabilities of the Limited Liability Company; the condemnation of the realty to the extent the award is not used for restoration; the receipt of insurance proceeds; and any other similar or extraordinary receipts or proceeds which in accordance with generally accepted accounting principles are attributable to capital, including transactions in connection with the termination and dissolution of the Limited Liability Company.

The "capital account" for each Member shall mean the account established, determined and maintained for such Member in accordance with Section 704(b) of the Internal Revenue Code and Treasury Regulation Section 1.704-1(b)(2)(iv). The capital account for each Member shall be increased by (1) the amount of money contributed by such Member to the Limited Liability Company, (2) the fair market value of property contributed by such Member to the Limited Liability Company (net of liabilities secured by such contributed property that the Limited Liability Company is considered to assume or take subject to under Section 752 of the Internal Revenue Code), and (3) allocations to such Member of Limited Liability Company income and gain (or items thereof), including income and gain exempt from tax and income and gain described in Trea. Reg. Section 1.704-1(b)(2)(iv)(g),

but excluding income and gain described in subsection (b)(4)(i) of said Regulation, and shall be decreased by (4) the amount of money distributed to such Member by the Limited Liability Company, (5) the fair market value of property distributed to such Member by the Limited Liability Company (net of liabilities secured by such distributed property that such Member is considered to assume or take subject to under Section 752 of the Code), (6) allocations to such Member of expenditures of the Limited Liability Company described in Section 705(a)(2)(B) of the Code, and (7) allocations of Limited Liability Company loss and deduction (or items thereof) including loss and deduction described in Trea. Reg. Section 1.704-1(b)(2)(iv)(g), but excluding items described in (6) above and loss or deduction described in subsections (b)(4)(i) or (b)(4)(iii) of said Regulation. Net profits and net losses of the Limited Liability Company from other than capital transactions, as of the end of any fiscal year or other period, shall be credited or charged to the capital accounts of the Members prior to any charge or credit to said capital accounts for net profits and net losses of the Limited Liability Company from capital transactions as of the end of such fiscal year or other period. The capital account for each Member shall be otherwise adjusted in accordance with the additional rules of Trea. Reg. Section 1.704-1(b)(2)(iv).

The term "Members' Percentage Interests" shall mean the percentages set forth opposite the name of each Member below:

Members	*Percentage Interest*
ARNOLD HOPLAND	Thirty-Four percent (34%)
JEFFREY HOPLAND	Thirty-Three percent (33%)
KENNETH HOPLAND	Thirty-Three percent (33%)

During each fiscal year, the net profits and net losses of the Limited Liability Company (other than from capital transactions), and each item of income, gain, loss, deduction or credit entering into the computation thereof, shall be credited or charged, as the case may be, to the capital accounts of each Member in proportion to the Members' Percentage Interests. The net profits of the Limited Liability Company from capital transactions shall be allocated in the following order of priority: (a) to offset any negative balance in the capital accounts of the Members in proportion to the amounts of the negative balance in their respective capital accounts, until all negative balances in the capital accounts have been eliminated; then (b) to the Members in proportion to the Members' Percentage Interests. The net losses of the Limited Liability Company from capital transactions shall be allocated in the following order of priority: (a) to the extent that the balances in the capital accounts of any Members are in excess of their original contributions, to

such Members in proportion to such excess balances in the capital accounts until all such excess balances have been reduced to zero; then (b) to the Members in proportion to the Members' Percentage Interests.

The cash receipts of the Limited Liability Company shall be applied in the following order of priority: (a) to the payment by the Limited Liability Company of amounts due on debts and liabilities of the Limited Liability Company other than to any Member, and operating expenses of the Limited Liability Company; (b) to the payment of interest and amortization due on any loan made to the Limited Liability Company by any Member; (c) to the establishment of cash reserves determined by the Members to be necessary or appropriate, including without limitation reserves for the operation of the Limited Liability Company's business, taxes and contingencies; and (d) to the repayment of any loans made to the Limited Liability Company by any Member. Thereafter, the cash receipts of the Limited Liability Company shall be distributed among the Members as hereafter provided.

Except as otherwise provided in this Agreement or required by law, distributions of cash receipts of the Limited Liability Company, other than from capital transactions, shall be allocated among the Members in proportion to the Members' Percentage Interests.

Except as otherwise provided in this Agreement or required by law, distributions of cash receipts from capital transactions shall be allocated in the following order of priority: (a) to the Members in proportion to their respective capital accounts until each Member has received cash distributions equal to any positive balance in his capital account; then (b) to the Members in proportion to the Members' Percentage Interests.

It is the intention of the Members that the allocations hereunder shall be deemed to have "substantial economic effect" within the meaning of Section 704 of the Internal Revenue Code and Trea. Reg. Section 1.704-1. Should the provisions of this Agreement be inconsistent with or in conflict with Section 704 of the Code or the Regulations thereunder, then Section 704 of the Code and the Regulations shall be deemed to override the contrary provisions hereof. If Section 704 or the Regulations at any time require that limited liability company operating agreements contain provisions which are not expressly set forth herein, such provisions shall be incorporated into this Agreement by reference and shall be deemed a part of this Agreement to the same extent as though they had been expressly set forth herein, and the Members shall amend the terms of this Agreement to add such provisions, and any such amendment shall be retroactive to whatever extent required to create allocations with a substantial economic effect.

9. Books, Records and Tax Returns

At all times during the continuance of the Limited Liability Company, the Members shall keep or cause to be kept complete and accurate records and books of account in which shall be entered each transaction of the Limited Liability Company.

The Limited Liability Company shall furnish to each Member, within seventy-five days after the end of each fiscal year, an annual report of the Limited Liability Company which shall include a balance sheet as of the end of such fiscal year; a profit and loss statement of the Limited Liability Company for such fiscal year; a statement of the balance in the capital account of such Member; and the amount of such Member's share of the Limited Liability Company's income, gain, losses, deductions and other relevant items for federal income tax purposes.

The Limited Liability Company shall prepare or cause to be prepared all federal, state and local income tax and information returns for the Limited Liability Company, and shall cause such tax and information returns to be filed timely with the appropriate governmental authorities. Within seventy-five days after the end of each fiscal year, the Limited Liability Company shall forward to each person who was a Member during the preceding fiscal year a true copy of the Limited Liability Company's information return filed with the Internal Revenue Service for the preceding fiscal year.

All elections required or permitted to be made by the Limited Liability Company under the Internal Revenue Code, and the designation of a tax matters partner pursuant to Section 6231(a)(7) of the Internal Revenue Code for all purposes permitted or required by the Code, shall be made by the Limited Liability Company by the affirmative vote or consent of Members holding a majority of the Members' Percentage Interests. The tax matters partner shall take such action as may be necessary to cause each other Member to become a notice member within the meaning of Section 6223 of the Code. The tax matters partner may not take any action contemplated by Sections 6222 through 6232 of the Code without the consent of the Limited Liability Company by the affirmative vote or consent of Members holding a majority of the Members' Percentage Interests. Until such time as otherwise change by the Members, ARNOLD HOPLAND is designated as the tax matters partner.

The Limited Liability Company shall furnish to each Member, promptly upon request, a current list of the names and addresses of all of the Members of the Limited Liability Company, and any other persons or entities having any financial interest in the Limited Liability Company.

10. Bank Accounts

All funds of the Limited Liability Company shall be deposited in the Limited Liability Company's name in such bank account or accounts as shall be designated by the Members. Withdrawals from any such bank accounts shall be made only in the regular course of business of the Limited Liability Company and shall be made upon such signature or signatures as the Members from time to time may designate.

11. Management of the Limited Liability Company

The business and affairs of the Limited Liability Company shall be conducted and managed by the Members in accordance with this Agreement and the laws of Tennessee.

Except as expressly provided elsewhere in this Agreement, all decisions respecting the management, operation and control of the business and affairs of the Limited Liability Company and all determinations made in accordance with this Agreement shall be made by the affirmative vote or consent of Members holding a majority of the Members' Percentage Interests.

The Members shall devote such time and attention as the Members deem necessary to the conduct and management of the business and affairs of the Limited Liability Company. The Members may hire such persons or entities as desirable to conduct the administrative affairs.

Each of the Members shall have authority to execute instruments on behalf of the Limited Liability Company.

The Members shall receive, as compensation for the services of the Members to the Limited Liability Company, such sums as may be determined from time to time by the affirmative vote or consent of Members holding a majority of the Members' Percentage Interests.

At all times, any and all decisions requiring professional medical judgment shall be decided only by a person or persons who are licensed physicians in the State of Tennessee.

The Members may appoint by majority consent such other officers as they desire and shall define the duties of the same at the time of election.

12. Assignment of Interests

Except as otherwise provided in this Agreement, no Member or other person holding any interest in the Limited Liability Company may assign, pledge, hypothecate, transfer or otherwise dispose of all or any part of his interest in the Limited Liability Company, including without limitation the capital, profits or distributions of the Limited Liability Company without the prior written consent of the other Members in each instance.

The Members agree that no Member may voluntarily withdraw from the Limited Liability Company without the unanimous vote or consent of the Members.

A Member may assign all or any part of such Member's interest in the allocations and distributions of the Limited Liability Company to any of the following (collectively the "permitted assignees"): any person, corporation, partnership or other entity as to which the Limited Liability Company has given consent to the assignment of such interest in the allocations and distributions of the Limited Liability Company by the unanimous vote or consent of the Members. An assignment to a permitted assignee shall only entitle the permitted assignee to the allocations and distributions to which the assigned interest is entitled, unless such permitted assignee applies for admission to the Limited Liability Company and is admitted to the Limited Liability Company as a Member in accordance with this Agreement.

An assignment, pledge, hypothecation, transfer or other disposition of all or any part of the interest of a Member in the Limited Liability Company or other person holding any interest in the Limited Liability Company in violation of the provisions hereof shall be null and void for all purposes.

No assignment, transfer or other disposition of all or any part of the interest of any Member permitted under this Agreement shall be binding upon the Limited Liability Company unless and until a duly executed and acknowledged counterpart of such assignment or instrument of transfer, in form and substance satisfactory to the Limited Liability Company, has been delivered to the Limited Liability Company.

No assignment or other disposition of any interest of any Member may be made if such assignment or disposition, alone or when combined with other transactions, would result in the termination of the Limited Liability Company within the meaning of Section 708 of the Internal Revenue Code or under any other relevant section of the Code or any successor statute. No assignment or other disposition of any interest of any Member may be made without an opinion of counsel satisfactory to the Limited Liability Company that such assignment or disposition is subject to an effective registration under, or exempt from the registration requirements of, the

applicable federal and state securities laws. No interest in the Limited Liability Company may be assigned or given to any person below the age of 21 years or to a person who has been adjudged to be insane or incompetent.

Anything herein contained to the contrary, the Limited Liability Company shall be entitled to treat the record holder of the interest of a Member as the absolute owner thereof, and shall incur no liability by reason of distributions made in good faith to such record holder, unless and until there has been delivered to the Limited Liability Company the assignment or other instrument of transfer and such other evidence as may be reasonably required by the Limited Liability Company to establish to the satisfaction of the Limited Liability Company that an interest has been assigned or transferred in accordance with this Agreement.

13. Right of First Refusal

If a Member desires to sell, transfer or otherwise dispose of all or any part of his interest in the Limited Liability Company, such Member (the "Selling Member") shall first offer to sell and convey such interest to the other Members before selling, transferring or otherwise disposing of such interest to any other person, corporation or other entity. Such offer shall be in writing, shall be given to every other Member, and shall set forth the interest to be sold, the purchase price to be paid, the date on which the closing is to take place (which date shall be not less than thirty nor more than sixty days after the delivery of the offer), the location within the State of Tennessee at which the closing is to take place, and all other material terms and conditions of the sale, transfer or other disposition.

Within fifteen days after the delivery of said offer the other Members shall deliver to the Selling Member a written notice either accepting or rejecting the offer. Failure to deliver said notice within said fifteen days conclusively shall be deemed a rejection of the offer. Any or all of the other Members may elect to accept the offer, and if more than one of the other Members elects to accept the offer, the interest being sold and the purchase price therefore shall be allocated among the Members so accepting the offer in proportion to their Members' Percentage Interests, unless they otherwise agree in writing. The purchase price for the purchasing Members shall be the lesser of the offer price or that amount according to Article 16, herein.

If any or all of the other Members elect to accept the offer, then the closing of title shall be held in accordance with the offer and the Selling Member shall deliver to the other Members who have accepted the offer an assignment of the interest being sold by the Selling Member, and said other Members shall pay the purchase price to the Selling Member.

If no other Member accepts the offer, or if the Members who have accepted such offer default in their obligations to purchase the interest, then the Selling Member within 120 days after the delivery of the offer may sell such interest to any other person or entity at a purchase price which is not less than the purchase price prescribed in the offer and upon terms and conditions which are substantially the same as the terms and conditions set forth in the offer, provided all other applicable requirements of this Agreement are complied with. An assignment of such interest to a person or entity who is not a Member of the Limited Liability Company shall only entitle such person or entity to the allocations and distributions to which the assigned interest is entitled, unless such person or entity applies for admission to the Limited Liability Company and is admitted to the Limited Liability Company as a Member in accordance with this Agreement.

If the Selling Member does not sell such interest within said 120 days, then the Selling Member may not thereafter sell such interest without again offering such interest to the other Members in accordance with this Article 13.

14. Admission of New Members

The Members may admit new Members (or transferees of any interests of existing Members) into the Limited Liability Company by the unanimous vote or consent of the Members. All Members must be licensed physicians in good standing in the State of Tennessee.

As a condition to the admission of a new Member, such Member shall execute and acknowledge such instruments, in form and substance satisfactory to the Limited Liability Company, as the Limited Liability Company may deem necessary or desirable to effectuate such admission and to confirm the agreement of such Member to be bound by all of the terms, covenants and conditions of this Agreement, as the same may have been amended. Such new Member shall pay all reasonable expenses in connection with such admission, including without limitation reasonable attorneys' fees and the cost of the preparation, filing or publication of any amendment to this Agreement or the Articles of Organization, which the Limited Liability Company may deem necessary or desirable in connection with such admission.

No new Member shall be entitled to any retroactive allocation of income, losses, or expense deductions of the Limited Liability Company. The Limited Liability Company may make pro rata allocations of income, losses or expense deductions to a new Member for that portion of the tax year in which the Member was admitted in accordance with Section 706(d) or the Internal Revenue Code and regulations thereunder.

In no event shall a new Member be admitted to the Limited Liability Company if such admission would be in violation of applicable federal or state securities laws or would adversely affect the treatment of the Limited Liability Company as a partnership for income tax purposes.

15. Withdrawal Events Regarding Members and Election to Continue the Limited Liability Company

In the event of the retirement, withdrawal, expulsion, or dissolution of a Member, or an event of bankruptcy or insolvency, as hereinafter defined, with respect to a Member, or the occurrence of any other event which terminates the continued membership of a Member in the Limited Liability Company pursuant to the laws of Tennessee (each of the foregoing being hereinafter referred to as a "Withdrawal Event"), the Limited Liability Company shall continue unless within ninety days after notice to the Members of such Withdrawal Event the remaining Members unanimously elect to discontinue the business. A Member shall be deemed withdrawn if: the Member is no longer licensed as a physician in the State of Tennessee, the Member's employment with the Limited Liability Company is terminated for any reason (voluntarily or involuntarily), the other Members unanimously agree to expel the Member from the Limited Liability Company or the Member has not worked a minimum of forty hours per work week for six consecutive months or a total of 120 non-consecutive days working less eight hours per work day over a period of nine months. In the event of a Withdrawal Event with respect to any Member, any successor in interest to such Member (including without limitation any executor, administrator, heir, committee, guardian, or other representative or successor) shall not become entitled to any rights or interest of such Member in the Limited Liability Company, other than the allocations and distributions to which such Member is entitled, unless such successor in interest is admitted as a Member in accordance with this Agreement.

An "event of bankruptcy or insolvency" with respect to a Member shall occur if such Member: applies for or consents to the appointment of a receiver, trustee or liquidator of all or a substantial part of his assets; or makes a general assignment for the benefit of creditors; or is adjudicated a bankrupt or an insolvent; or files a voluntary petition in bankruptcy or a petition or an answer seeking an arrangement with creditors or to take advantage of any bankruptcy, insolvency, readjustment of debt or similar law or statute, or an answer admitting the material allegations of a petition filed against him in any bankruptcy, insolvency, readjustment of debt or similar proceedings; or takes any action for the purpose of effecting any of the foregoing; or an order, judgment or decree shall be entered, with or without the application, approval or consent of such Member, by any court of competent jurisdiction, approving a petition for or appointing a receiver or trustee of all or a

substantial part of the assets of such Member, and such order, judgment or decree shall continue unstayed and in effect for thirty days.

Furthermore, in the event of the death or withdrawal of a Member, within 60 days after the appointment and qualification of the legal representative or representatives of a deceased Member, or within 60 days of the withdrawal of the Member, or within 120 days after the date of death of a deceased Member if no such legal representative is appointed, such legal representative or representatives or the heirs, distributees or beneficiaries of the deceased Member, or the withdrawing Member, as the case may be, and each successor in interest to the Member's total percentage of ownership of Company (Membership Interest) of the deceased or withdrawing Member, shall offer to sell to the remaining Members all of the Membership Interest of the deceased or withdrawing Member. The remaining Members must in writing indicate to the offeror within 30 days of the receipt of the offer whether such offer will be accepted.

The purchase price for the Membership Interest purchased pursuant to this Article 15 shall be determined in accordance with the provisions of Article 16 below.

When the Membership Interest of a deceased or withdrawing Member is purchased pursuant to the provisions of this Article 15, the purchasers shall pay the purchase price for the Membership Interest to the deceased Member's estate or the withdrawing Member in cash or by certified check or as otherwise agreed between the purchasing Member and the deceased Member's representative, within 45 days after acceptance of the offer. Upon receipt of the purchase price, the estate of the deceased Member or the withdrawing member shall cause to be delivered to the Company documentation evidencing the Membership Interest of the deceased or withdrawing Member, with any other instruments required by the Company, including estate or inheritance tax waivers, so that full and complete title to the Membership Interest can be transferred on the books of the Company when the Membership Interest of the deceased or withdrawing Member has been so transferred.

16. Purchase Price

For purposes of purchases of Membership Interest pursuant to the provisions of this Agreement, the purchase price shall be as follows (unless otherwise stated in the Agreement).

The parties hereto agree that the purchase price for the entirety of the Membership Interests shall be _____. The purchase price to be applied for purchase of a specific Member's interest shall be that the proportional amount of the whole for the interests to be purchased. The purchase

price may be adjusted annually by the unanimous consent of the Members. If no adjustment is made then the purchase price shall remain the same as last set by the Members.

17. Dissolution and Liquidation

The Limited Liability Company shall terminate upon the occurrence of any of the following: the election by the Members to dissolve the Limited Liability Company made by the unanimous vote or consent of the Members; the occurrence of a Withdrawal Event with respect to a Member and the failure of the remaining Members to elect to continue the business of the Limited Liability Company as provided for in Article 15 above; or any other event which pursuant to this Agreement, as the same may hereafter be amended, shall cause a termination of the Limited Liability Company.

The liquidation of the Limited Liability Company shall be conducted and supervised by a person designated for such purposes by the affirmative vote or consent of Members holding a majority of the Members' Percentage Interests (the "Liquidating Agent"). The Liquidating Agent hereby is authorized and empowered to execute any and all documents and to take any and all actions necessary or desirable to effectuate the dissolution and liquidation of the Limited Liability Company in accordance with this Agreement.

Promptly after the termination of the Limited Liability Company, the Liquidating Agent shall cause to be prepared and furnished to the Members a statement setting forth the assets and liabilities of the Limited Liability Company as of the date of termination. The Liquidating Agent, to the extent practicable, shall liquidate the assets of the Limited Liability Company as promptly as possible, but in an orderly and businesslike manner so as not to involve undue sacrifice.

The proceeds of sale and all other assets of the Limited Liability Company shall be applied and distributed in the following order of priority: (a) to the payment of the expenses of liquidation and the debts and liabilities of the Limited Liability Company, other than debts and liabilities to Members; (b) to the payment of debts and liabilities to Members; (c) to the setting up of any reserves which the Liquidating Agent may deem necessary or desirable for any contingent or unforeseen liabilities or obligations of the Limited Liability Company, which reserves shall be paid over to an attorney-at-law admitted to practice in the State of Tennessee as escrowee, to be held for a period of two years for the purpose of payment of the aforesaid liabilities and obligations, at the expiration of which period the balance of such reserves shall be distributed as hereinafter provided; (d) to the Members in proportion to their respective capital accounts until each Member has received cash distributions equal to any positive balance in his capital account,

in accordance with the rules and requirements of Trea. Reg. Section 1.704-1(b)(2)(ii)(b); and (e) to the Members in proportion to the Members' Percentage Interests.

The liquidation shall be complete within the period required by Trea. Reg. Section 1.704-1(b)(2)(ii)(b).

Upon compliance with the distribution plan, the Members shall cease to be such, and the Limited Liability Company shall execute, acknowledge and cause to be filed such certificates and other instruments as may be necessary or appropriate to evidence the dissolution and termination of the Limited Liability Company.

18. Representations Of Members

Each of the Members represents, warrants and agrees that the Member is acquiring the interest in the Limited Liability Company for the Member's own account for investment purposes only and not with a view to the sale or distribution thereof; the Member, if an individual, is over the age of 21; if the Member is an organization, such organization is duly organized, validly existing and in good standing under the laws of its state of organization and that it has full power and authority to execute this Agreement and perform its obligations hereunder; the execution and performance of this Agreement by the Member does not conflict with, and will not result in any breach of, any law or any order, writ, injunction or decree of any court or governmental authority against or which binds the Member, or of any agreement or instrument to which the Member is a party; and the Member shall not dispose of such interest or any part thereof in any manner which would constitute a violation of the Securities Act of 1933, the Rules and Regulations of the Securities and Exchange Commission, or any applicable laws, rules or regulations of any state or other governmental authorities, as the same may be amended.

19. Notices

All notices, demands, requests or other communications which any of the parties to this Agreement may desire or be required to give hereunder shall be in writing and shall be deemed to have been properly given if sent by express courier or by registered or certified mail, return receipt requested, with postage prepaid, addressed as follows: (a) if to the Limited Liability Company, to the Limited Liability Company at the principal place of business of the Limited Liability Company heretofore stated or to such other address or addresses as may be designated by the Limited Liability Company by notice to the Members pursuant to this Article 19; and (b) if to any Member, to the address of said Member first above

written, or to such other address as may be designated by said Member by notice to the Limited Liability Company and the other Members pursuant to this Article 19.

20. Arbitration

Any dispute, controversy or claim arising out of or in connection with this Agreement or any breach or alleged breach hereof shall, upon the request of any party involved, be submitted to, and settled by, arbitration in the city in which the principal place of business of the Limited Liability Company is then located, pursuant to the commercial arbitration rules then in effect of the American Arbitration Association (or at any other time or place or under any other form of arbitration mutually acceptable to the parties involved). Any award rendered shall be final and conclusive upon the parties and a judgment thereon may be entered in a court of competent jurisdiction. The expenses of the arbitration shall be borne equally by the parties to the arbitration, provided that each party shall pay for and bear the cost of its own experts, evidence and attorneys' fees, except that in the discretion of the arbitrator any award may include the attorneys' fees of a party if the arbitrator expressly determines that the party against whom such award is entered has caused the dispute, controversy or claim to be submitted to arbitration as a dilatory tactic or in bad faith.

21. Amendments

This Agreement may not be altered, amended, changed, supplemented, waived or modified in any respect or particular unless the same shall be in writing and agreed to by the affirmative vote or consent of Members holding a majority of the Members' Percentage Interests. No amendment may be made to Articles 6, 8, 12 and 16 hereof, insofar as said Articles apply to the financial interests of the Members, except by the vote or consent of all of the Members. No amendment of any provision of this Agreement relating to the voting requirements of the Members on any specific subject shall be made without the affirmative vote or consent of at least the number or percentage of Members required to vote on such subject.

22. Miscellaneous

This Agreement and the rights and liabilities of the parties hereunder shall be governed by and determined in accordance with the laws of the State of Tennessee. If any provision of this Agreement shall be invalid or unenforceable, such invalidity or unenforceability shall not affect the other provisions of this Agreement, which shall remain in full force and effect.

The captions in this Agreement are for convenience only and are not to be considered in construing this Agreement. All pronouns shall be deemed to be the masculine, feminine, neuter, singular or plural as the identity of the person or persons may require. References to a person or persons shall include partnerships, corporations, limited liability companies, unincorporated associations, trusts, estates and other types of entities.

This Agreement, and any amendments hereto may be executed in counterparts all of which taken together shall constitute one agreement.

This Agreement sets forth the entire agreement of the parties hereto with respect to the subject matter hereof. It is the intention of the Members that this Agreement shall be the sole source of agreement of the parties, and, except to the extent a provision of this Agreement provides for the incorporation of federal income tax rules or is expressly prohibited or ineffective under the Tennessee Revised Limited Liability Company Act (Tenn. Code Ann. §48-249-101 et seq.) and more specifically the Tennessee Professional Revised Limited Liability Company Act (Tenn. Code Ann. Section 48-249-1101 et seq.), this Agreement shall govern even when inconsistent with, or different from, the provisions of any applicable law or rule. To the extent any provision of this Agreement is prohibited or otherwise ineffective under the Tennessee Revised Limited Liability Company Act (Tenn. Code Ann. §48-249-101 et seq.) and more specifically the Tennessee Professional Revised Limited Liability Company Act (Tenn. Code Ann. Section 48-249-1101 et seq.), such provision shall be considered to be ineffective to the smallest degree possible in order to make this Agreement effective under the Tennessee Revised Limited Liability Company Act (Tenn. Code Ann. §48-249-101 et seq.) and more specifically the Tennessee Professional Revised Limited Liability Company Act (Tenn. Code Ann. Section 48-249-1101 et seq.). If the Tennessee Revised Limited Liability Company Act (Tenn. Code Ann. §48-249-101 et seq.) and more specifically the Tennessee Professional Revised Limited Liability Company Act (Tenn. Code Ann. Section 48-249-1101 et seq.) is subsequently amended or interpreted in such a way to make any provision of this Agreement that was formerly invalid valid, such provision shall be considered to be valid from the effective date of such interpretation or amendment.

Subject to the limitations on transferability contained herein, this Agreement shall be binding upon and inure to the benefit of the parties hereto and to their respective heirs, executors, administrators, successors and assigns.

No provision of this Agreement is intended to be for the benefit of or enforceable by any third party.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement on the date first above written.

MEDICAL CARE, PLLC

ARNOLD HOPLAND, Member

JEFFREY HOPLAND, Member

KENNETH HOPLAND, Member

Attachment A-4

The Applicant, Medical Care, PLLC, is a member managed Tennessee medical professional limited liability company. The existing members of Medical Care, PLLC and each of their respective percentage ownership interests in the company are as follows:

Member	Percentage Interest
Arnold Hopland, M.D.	33.33%
Jeff Hopland, M.D.	33.33%
Kenny Hopland, M.D.	33.33%

Neither the Applicant nor any of its owners have a financial interest in any other "health care institution" as defined in Tennessee Code Annotated §68-11-1602 in Tennessee.

The Applicant is managed by Pine Palms Management, LLC, a Tennessee limited liability company. The current CEO is Steve Hopland. The members of Pine Palms Management, LLC and each of their respective percentage ownership interests in the company are as follows:

Member	Percentage Interest
Arnold Hopland, M.D.	20%
Steve Hopland	20%
Jeff Hopland, M.D.	20%
Jenny Whaley	20%
Kenny Hopland, M.D.	20%

Attachment A-5

MANAGEMENT SERVICES AGREEMENT

THIS MANAGEMENT SERVICES AGREEMENT (this "Agreement") is made and entered into as of March 1, 2013, by and between **Pine Palms Management, LLC** a Tennessee limited liability company (the "Manager") and **Medical Care, PLLC**, a Tennessee limited liability company (the "Owner"), which intends to owns and operates an magnetic resonance imaging (MRI) at Medical Care, PLLC located at 1500 West Elk Ave, Elizabethton, Tennessee (the "MRI"). This agreement is contingent on the successful approval of certificate of need to establish MRI services. If such approvals are not received before December 31, 2013 this agreement is null and void with no further obligation to either party.

I. GENERAL

1. The Owner hereby retains the Manager for the purpose of rendering management, administration and purchasing services and support, and all other management support needed for operation, and in the best interest, of the MRI on the basis hereafter set forth, consistent with the mission of Owner and subject to the policies established by the Owner, which policies shall be consistent with applicable state and federal law.

2. The Manager shall perform all of the services described in Article II and Article III hereof for the account of and as agent of the Owner. All such services shall be rendered using the Manager's best efforts and subject to the control of the Owner, which shall have final authority in all matters relating to the MRI's operations.

3. The Owner hereby appoints the Manager its attorney-in-fact with full power on its behalf and in its name, or in the name of the MRI, to enter into contracts relating to the affairs of the MRI; provided, however, the Manager shall not incur any obligation for repairs, equipment, additions or betterments if to do so would exceed budgeted expenditure levels (whether capital or operating) without first requesting the consent of Owner. In the event that Owner does not respond in writing to Manager's expenditure request within five (5) days of receipt thereof, then such expenditure shall be deemed approved by Owner.

4. Except in the event of the merger or consolidation of the Manager, or the sale by the Manager of substantially all of its assets, the Manager shall not assign this Agreement, other than to a subsidiary corporation or other entity controlled by or under common control with the Manager, without the written consent of the Owner, which consent shall not be unreasonably withheld.

5 The term of this Agreement shall commence as of the date set forth in the preamble of this Agreement and shall continue for a term of five (5) years through March 1, 2018 unless this Agreement is terminated pursuant to this Article I. This Agreement shall automatically renew for additional successive terms of one (1) year each unless one party gives the other party sixty (60) days prior written notice of termination before the expiration of the then current term.

6. The Owner shall have the right to terminate this Agreement upon the Manager's material breach of this Agreement. In the event termination is for an alleged material breach by the Manager, such notice shall describe in detail the basis upon which the Owner believes such termination is justified. Upon receipt of such notice, the Manager shall have ninety (90) days (or thirty (30) days in the event that the Manager's breach materially and adversely affects patient safety and quality of care) during which to attempt to cure any alleged default under this Agreement, and upon such cure being effected, the Owner's rights to terminate shall cease and this Agreement will continue in full force and effect. Furthermore, if the Manager has diligently attempted to effect such a cure within such cure period but cannot complete such cure because of the failure of a third party (such as a governmental agency) to act within such period, then the Manager shall have a reasonable time beyond such cure period to complete its cure of the alleged basis for the Owner's election to terminate.

7. The Manager shall have the right to terminate this Agreement upon the Owner's material breach of this Agreement. In the event termination is for an alleged material breach by the Owner, such notice shall describe in detail the basis upon which the Manager believes such termination is justified. Upon receipt of such notice, the Owner shall have ninety (90) days (or thirty (30) days in the event that the Owner's breach materially and adversely affects patient safety and quality of care) during which to attempt to cure any alleged default under this Agreement, and upon such cure being effected, the Manager's rights to terminate shall cease and this Agreement will continue in full force and effect. Furthermore, if the Owner has diligently attempted to effect such a cure within such cure period but cannot complete such cure because of the failure of a third party (such as a governmental agency) to act within such period, then the Owner shall

have a reasonable time beyond such cure period to complete its cure of the alleged basis for the Manager's election to terminate. Notwithstanding the foregoing, Manager shall have the right to suspend the provision of services under this Agreement in the event that Owner fails to pay any of the compensation payable pursuant to Article IV as and when due.

8. If either party shall appoint or consent to the appointment of a receiver, trustee or liquidator of such party or of all or a substantial part of its assets, file a voluntary petition in bankruptcy, make a general assignment for the benefit of creditors, file a petition or an answer seeking reorganization or arrangements with creditors or to take advantage of any insolvency law, or if an order, judgment or decree shall be entered by any court of competent jurisdiction, on the application of a creditor, adjudicating such party bankrupt or insolvent, and such order, judgment or decree shall continue unstayed and in effect for any period of ninety (90) days, then, in case of any such event, the term of this Agreement shall terminate, at the option of the non-defaulting party, upon written notice to the other party.

9. In addition to the foregoing, after the first anniversary of the effective date of this Agreement, either party may terminate this Agreement, without cause, upon not less than ninety (90) days prior written notice.

II. MANAGEMENT SERVICES

1. Subject to the provisions of Article I, the Manager will render all services, direction, advice, supervision and assistance in the operation of the MRI as necessary, including, but in no way limited to, the following:

A. Obtain and maintain the accreditation and state licensing of the MRI with the proper agencies and insurance companies including ACR or equivalent.

B. Hiring, supervising, directing, leasing and discharging, on behalf of the Owner, all personnel performing services at the MRI including the administrator of the MRI (the "Administrator"), as needed. All MRI personnel shall be employees of the Manager.

C. Negotiating fee payment methods, in coordination with the Owner, including Medicare reimbursement, with the appropriate third party payors and state and federal agencies;

D. Establishing staffing schedules, wage structures and personnel policies for all personnel;

E. Determining and setting patient charges for MRI services;

F. Providing policies and operating procedures to all departments;

G. Providing for the purchase, lease or disposition by the Owner of all supplies and equipment including information systems hardware and software used in the operation of the MRI;

I. Directing the day-to-day operations of the MRI to insure the operations are conducted in a businesslike manner consistent with the policies adopted by Owner from time to time;

J. Performing all management and non-medical oversight responsibilities for the Owner;

K. Negotiating or retaining on behalf of the Owner contractual relationships for radiologist services, and other professional services as appropriate;

III. ACCOUNTING AND BOOKKEEPING SERVICES

1. The Manager agrees to provide or cause to be provided the following accounting and bookkeeping services for the Owner in the operation of the MRI:

A. Receipt for and deposit of all funds received from the operation of the MRI and supervise the disbursement of such funds for the operating expenses of the MRI.

B. Maintain the books of account, including all journals and ledgers, check register and payroll records;

C. Post all patient and other charges, including necessary analysis and corrections;

D. Establish adequate receivables, credit and collection policies and procedures;

E. Process vendors' invoices and other accounts payable;

F. Prepare or contract for processing payroll checks from time sheet summaries prepared under the Manager's supervision;

G. Prepare payroll and supervise preparation of the Owner's tax returns

H. Prepare monthly bank reconciliations;

I. Prepare monthly profit and loss statements, the format of which shall be compatible with the information systems of the Owner;

J. Establish patient billing procedures;

K. Conduct monthly meetings with the Owner's personnel, either telephonically or on-site as required; and

L. Handle patient complaints.

The Manager shall be permitted to contract for these services with an independent accounting firm or other qualified provider, provided that any expenses incurred for such outside services shall be considered to be part of the fee set forth in Article IV below.

IV. FEES FOR SERVICES AND REIMBURSABLE EXPENSES

As compensation for performing the management services required hereunder, Owner shall pay to Manager a management fee of 15% of gross collections which include the management, billing & computer support services, In addition, Manager shall be reimbursed on a monthly basis for its direct expenses incurred in connection with the management of the MRI including but not limited to (i)personnel required for daily operations , (ii) supplies and inventory (iii) equipment, maintenance and repairs (iv) Rents (v)Manager's reasonable out-of-pocket expenses; (vi) legal fees, accounting, and other professional fees incurred by Manager on behalf of Owner, and (vii) other direct expenses incurred by Manager on behalf of Owner. Manager shall submit, as requested by Owner from time to time, appropriate written documentation supporting such expenses.

Owner hereby grants to Manager the right to pay to Manager all fees and reimbursable expenses hereunder from funds received from the operation of the MRI.

V. INSURANCE

During the term of this Agreement, Owner shall, at its sole cost and expense, obtain and maintain with commercial carriers acceptable to Manager appropriate professional, casualty and comprehensive general liability insurance covering the Owner and its personnel in such amounts, on such basis and upon such terms and conditions as Owner and Manager deem appropriate.

The casualty and comprehensive general liability insurance shall insure against loss of or physical damage to the MRI and the furniture, fixtures and equipment therein, under standard all-risk coverage (including but not limited to fire, smoke, lightening, wind storm, explosion, aircraft or vehicle damage, riot, civil commotion, vandalism and malicious mischief) and shall also include damage due to flood and earthquake unless waived by Manager.

Manager shall be named an additional insured under all insurance policies procured by Owner hereunder. The right of Manager to invoke the protection of such policies shall be severable from and independent of the Owner's rights, and these policies shall not be terminable or non-renewable except upon thirty (30) days' written notice to Manager. No later than thirty (30) days following the execution of this Agreement and thirty (30) days following the end of each policy year, Owner shall give to Manager a copy of the endorsements naming Manager an additional insured. Such insurance policies shall contain endorsements which reflect the primary liability of the Owner's insurance carrier for all covered losses provided for herein, notwithstanding any insurance which may be maintained by Manager or any affiliate of Manager. Owner hereby waives any right of contribution with respect to the loss covered under such policies (or with respect to deductibles thereunder) against Manager or any of Manager's insurance carriers.

VI. INDEPENDENT CONTRACTORS

The relationship created hereby is that of an agent (Manager) contracting with a principal (Owner) as independent contractors. Neither of the parties hereto, nor their employees or agents, shall be construed to be the agent, employee, partner or representative of the other party, except as may be expressly provided for herein to the contrary.

VII. CONFIDENTIAL INFORMATION

As used in this Agreement, the term confidential information (the "Confidential Information") shall include the following: (i) all documents and other materials, including but not limited to, all memoranda, clinical manuals, handbooks, production books, educational material and audio or visual recordings, which contain information relating to the operation of the MRI or its programs (excluding written materials distributed to patients in the operation of the MRI as promotion for the MRI), (ii) all methods, techniques and procedures utilized in providing services to patients in the MRI not readily available through sources in the public domain, and (iii) all trademarks, trade names, service marks, or protected software of Manager and their related data files.

The Owner acknowledges and agrees that the Confidential Information is owned by the Manager and has been disclosed to it in confidence and with the understanding that it constitutes valuable business information developed by the Manager at great expenditure of time, effort and money. The Owner agrees that it shall not, without the express prior written consent of the Manager, use the Confidential Information for any purpose other than the performance of this Agreement. The Owner further agrees to keep strictly confidential and hold in trust all Confidential Information and not disclose or reveal such information to any third party without the express prior consent of the Manager.

Upon termination of this Agreement by either party for any reason whatsoever, the Owner shall forthwith return to the Manager all material constituting or containing Confidential Information and the Owner shall not thereafter use, appropriate, or reproduce such information or disclose such information to any third party.

The provisions of this Article VIII shall survive any termination or expiration of this Agreement. Manager shall have the right to use any Confidential Information and any technical or business expertise obtained during the course of its engagement hereunder in connection with its management of any other facility.

VIII. NOTICES

All notices permitted or required by this Agreement shall be deemed given when in writing and delivered personally via overnight courier or deposited in the United States mail, postage prepaid, return receipt requested, addressed to the other party at the address set forth below or such other address as the party may designate in writing:

To the Owner: Medical Care, PLLC
1500 West Elk Ave
Elizabethton, Tennessee 37643

To the Manager: Pine Palms Management, LLC
401 East Main Street
Johnson City, Tennessee 37601

IX. INDEMNIFICATION

1. Owner agrees to indemnify and hold harmless Manager, its affiliates and shareholders and their respective shareholders, directors, officers, employees and agents (collectively, a "Manager Indemnified Party") from and against any and all losses, claims, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses related to the defense of any claims) (a "Loss"), which may be asserted against any of the Manager Indemnified Parties or for which they may now or hereafter become subject arising in connection with the activities of the MRI, including without limitation matters relating to: (i) alleged or actual failure by the governing body, board of directors and/or similar body of Owner to perform any of its duties under this Agreement; (ii) any pending or threatened medical malpractice or other tort claims asserted against Manager relating to the MRI; (iii) any action against Manager brought by any of the MRI's current or former employees or medical staff members; (iv) any act or omission by any MRI employee, medical staff member or other personnel; and (v) any violation of any requirement applicable to the MRI under any federal, state or local environmental, hazardous waste or similar law or regulation; provided that such Loss (a) has not been caused by the gross negligence, willful misconduct or illegal conduct of Manager or the Manager Indemnified Party seeking indemnification pursuant to this Agreement or (b) is not related to a breach by Manager or any of its contractual obligations to Owner arising under this Agreement.

2. Manager agrees to indemnify and hold harmless the Owner and its members, partners, or shareholders (as appropriate), its directors or governors (as appropriate), and its officers, employees and agents (collectively, an "Owner Indemnified Party") from and against all Loss which may be asserted against any Owner Indemnified Party as a result of the gross negligence, willful misconduct or illegal conduct of Manager or a material breach of Manager's obligations under this Agreement in connection with the performance by Manager of its duties hereunder; provided that such Loss has not been caused by the gross negligence, willful misconduct or illegal conduct of the Owner or the Owner Indemnified Party seeking indemnification pursuant to this Agreement.

X. MISCELLANEOUS

1. This Agreement shall be construed to be in accordance with any and all federal and state laws, including laws relating to Medicare, TennCare, Medicaid, and other third party payers. In the event there is a change in such laws, whether by statute, regulation, agency or judicial decision, that has any material effect on any term of this Agreement, or in the event that counsel to one party determines that any term of this Agreement poses a risk of violating such laws, then the applicable term(s) of this Agreement shall be subject to renegotiation and either party may request renegotiation of the affected term or terms of this Agreement, upon written notice to the other party, to remedy such condition. In the interim, the parties shall perform their obligations hereunder in full compliance with applicable law.

The parties expressly recognize that upon request for renegotiation, each party has a duty and obligation to the other only to renegotiate the affected term(s) in good faith and, further, the parties expressly agree that their consent to proposals submitted by the other party during renegotiation efforts shall not be unreasonably withheld.

Should the parties be unable to renegotiate the term or terms so affected so as to bring such term or terms into compliance with the statute, regulation or judicial opinion that rendered same unlawful or unenforceable within thirty (30) days of the date on which notice of a desired renegotiation is given, then either party shall be entitled, after the expiration of said thirty (30) day period, to terminate this Agreement upon sixty (60) additional days written notice to the other party.

2. Article headings are for convenience of reference only and shall not be used to construe the meaning of any provision of this Agreement.

3. This Agreement may be executed in any number of counterparts, each of which shall be an original and all of which shall together constitute one Agreement.

4. Should any part of this Agreement be invalid or unenforceable, such invalidity or unenforceability shall not affect the validity and enforceability of the remaining portions.

5. Each individual signing this Agreement warrants that such execution has been duly authorized by the party for which he is signing. The execution and performance of this Agreement by each party has been duly authorized by all applicable laws and regulations and all necessary corporate action, and this Agreement constitutes the valid and enforceable obligation of each party in accordance with its terms.

6. This Agreement shall be construed in accordance with the laws of the State of Tennessee.

7. This Agreement may not be modified except in writing executed by the party to be charged.

8. This Agreement constitutes the entire Agreement of the parties hereto and supersedes all prior agreements and representations with respect to the subject matter hereof.

IN WITNESS WHEREOF, the parties have executed this Agreement on the date first above written.

MANAGER:

PINE PALMS MANGEMENT, LLC

By: _____
Title: CEO

OWNER:

MEDICAL CARE, PLLC

By: _____
Title: _____

Attachment A, 6.

MRI LICENSE AGREEMENT

THIS MRI LICENSE AGREEMENT (this "Agreement"), is made and entered into as of the 20th day of November, 2014, by and between **MOUNTAIN STATES HEALTH ALLIANCE d/b/a D/B/A SYCAMORE SHOALS HOSPITAL**, a Tennessee nonprofit corporation ("Hospital"), and **MEDICAL CARE, PLLC**, a Tennessee professional limited liability company ("PLLC").

WITNESSETH:

WHEREAS, PLLC desires to engage Hospital to provide it with certain medical facility space and equipment upon the terms and conditions set forth herein to assist PLLC to provide Magnetic Resonance Imaging Services ("MRI Services") to its patients in need of such services; and

WHEREAS, Hospital desires to provide PLLC with certain medical facility space and equipment for that purpose, upon the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual terms, covenants and conditions set forth herein, the parties mutually agree as follows:

1. Term. The term of this Agreement shall commence on December 1, 2014 (the "Commencement Date"), and shall continue for a period of ten (10) years (the "Initial Term"); thereafter, the Agreement shall renew automatically for one-year terms unless either party gives the other party written notice at least 90 days prior to the renewal date that they do not wish to renew the Agreement (the Initial Term and any renewals shall be collectively referred to herein as the "Term").

2. Resources to be Provided by Hospital. During the Term, Hospital shall furnish the following:

(a) License to Use Premises. Hospital shall permit PLLC to use that certain medical facility space identified on **EXHIBIT A** attached hereto, together with the furnishings and fixtures located therein and the non-exclusive right in common with the Hospital to use, enjoy and occupy the common areas of the facility (collectively, the "Premises"), for the sole purpose of providing MRI Services to its patients during periods of scheduled use as set forth below. Hospital shall also permit PLLC to use two (2) storage lockers located on the Premises (the "Lockers"). Hospital reserves the right to rearrange the Premises to use the space in a more efficient manner, provided the rearrangement does not unreasonably interfere with PLLC's use of the Premises for the purposes permitted hereunder. Hospital shall make all arrangements for, and pay all costs associated with, the utilities necessary for the operation of the Premises, including, without limitation, electricity, air conditioning, heat, water, gas, telephone, snow removal, waste (office and medical) collection and removal, and janitorial services at the Premises. Such costs are included in the Monthly Fees payable by PLLC pursuant to Section 3(a) below.

(b) License to Use Equipment. In addition to the space and furnishings referred to in Section 2(a) above, Hospital shall permit PLLC to use, and PLLC may use the equipment and other personal property described on **EXHIBIT B** attached hereto, together with any and all upgrades that Hospital hereafter determines are necessary or appropriate (collectively, the "MRI Unit") during periods of scheduled use as defined below. The parties acknowledge and agree that

at some point during the Term of this Agreement, Hospital intends to install a new MRI unit and related personal property (collectively the "New MRI Unit") on the Premises. During the installation and transition to the New MRI Unit, the parties agree that the Hospital shall make available to PLLC for its use a mobile MRI unit ("Mobile MRI"), if necessary, so that PLLC may provide the MRI Services to its patients without interruption (the MRI Unit, New MRI Unit, and Mobile MRI shall hereinafter sometimes be collectively referred to as the "Equipment"). PLLC shall use the Equipment solely for the purpose of providing MRI Services to its patients. PLLC acknowledges that the terms and conditions of this Agreement are subject and subordinate to the terms and conditions contained in any financing, security interest, mortgage, lien or other encumbrance Hospital may, in its sole discretion, place upon the Equipment through an unaffiliated third party. The terms of such financing and related documents (the "Equipment Acquisition Documents") are incorporated into this Agreement by this reference as if they were set out in full. PLLC shall not do anything that would constitute a breach of the terms and conditions of the Equipment Acquisition Documents and shall be bound by all terms contained therein governing use and possession of the Equipment. PLLC acknowledges that title to the Equipment shall remain with Hospital, subject to the interests of any Equipment lessor and any other party to whom Hospital grants a security interest in the Equipment. PLLC shall take no action that it knows would have the likely effect of encumbering Hospital's title or interest in the Equipment.

(c) No Warranty; Office Maintenance and Services. PLLC acknowledges that Hospital is not the manufacturer of the Equipment or the manufacturers' agent. ACCORDINGLY, PLLC HEREBY ACCEPTS USE OF THE EQUIPMENT AND THE PREMISES IN AN "AS IS" CONDITION. HOSPITAL HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY AS TO ANY MATTER WHATSOEVER RELATING TO THE EQUIPMENT OR THE PREMISES, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE DESIGN, FUNCTION OR CONDITION OF THE EQUIPMENT AND THE PREMISES, THE CONFORMANCE OF THE EQUIPMENT TO THE PROVISIONS AND SPECIFICATIONS OF ANY PURCHASE ORDER RELATING THERETO, THE FITNESS OF THE EQUIPMENT FOR ANY PARTICULAR PURPOSE, THE MERCHANTABILITY OF THE EQUIPMENT AND THE CONFORMANCE OF THE EQUIPMENT WITH APPLICABLE PATENT LAWS.

PLLC shall promptly notify Hospital if it becomes aware of any problem or defect in the Equipment or the Premises. Hospital shall make arrangements for the necessary repair and maintenance of the Equipment or the Premises, either through a service contract or otherwise; provided, however, that repair of any problem or defect caused by PLLC's negligent or intentional acts or omissions shall be made at the sole cost and responsibility of PLLC. In addition, if Hospital acquires any hardware or software upgrades that the manufacturers/servicing agents for the Equipment makes available, then it shall furnish the same to PLLC. However, Hospital shall have no obligation to obtain or provide any such upgrades, and PLLC shall bear the costs of any training necessary to instruct its personnel with respect to any upgrades on the Equipment.

(d) Supplies. PLLC shall be responsible for all supplies that PLLC determines are necessary or appropriate for PLLC's provision of MRI Services at the Premises, including office and medical supplies (the "Supplies"). Hospital shall not provide any Supplies, including, without limitation, any contrast material.

(e) Personnel. PLLC shall be responsible for its own diagnostic-imaging technician (the "Technician") for operation of the Equipment at the Premises, and its own physician

personnel for the professional interpretation or analysis of any MRI scan or image performed during PLLC's use of the Equipment. PLLC shall require the Technician to obtain and maintain all education and training necessary to be certified by applicable certifying/licensing agencies and/or the manufacturer of the Equipment to safely operate the Equipment and to comply with the requirements of regulatory and accrediting bodies that are applicable to the services provided by PLLC using the Premises and the Equipment. From time-to-time, upon request from the Hospital, PLLC shall provide the Hospital with sufficient evidence of the Technician's training and applicable certification, accreditation or licensure. PLLC shall also provide its own personnel, or arrange for personnel, to register PLLC's patients at the Premises.

(f) Schedule of Use. PLLC shall be entitled to the use of the Premises and Equipment on a part-time basis, in block times of four hours, to provide MRI Services to its patients pursuant to the schedule set forth in **EXHIBIT C** attached hereto (the "Block Times"). PLLC shall schedule and perform procedures during each Block Time, so that PLLC's use of the Premises and the Equipment is fully completed and PLLC personnel and patients have vacated the Premises with the Equipment ready for use by the Hospital immediately following the end of each Block Time of use by PLLC. If PLLC does not timely vacate the Premises with the Equipment ready for use by hospital at the end of any Block time, then PLLC shall pay to Hospital a holdover fee equal to twice the applicable Lease Fee set forth in Section 3(a) below. On each anniversary of the Commencement Date, the parties may mutually agree to adjust the PLLC's Block Times. PLLC specifically accepts the financial risk of scheduling adequate patient loads during periods of scheduled use and acknowledges that it shall not be entitled to any refund of compensation or other credit for any periods during which it is scheduled for use but has no scheduled patients.

3. Compensation to Hospital.

(a) Fees for Premises, Lockers, Equipment, Technicians, etc. In consideration of the Premises, Lockers, Equipment, and other items and services provided by Hospital under Section 2 above, PLLC shall pay to Hospital a fixed fee as follows (the "Lease Fees"):

(i) Eight Hundred and Seventeen Dollars ($817.00) per each four (4) hours of Block Time during which the MRI Unit and Mobile MRI are used by PLLC.

(ii) One Thousand and Twenty Four Dollars ($1,024.00) per each four (4) hours of Block Time during which the New MRI Unit is used by PLLC.

(iii) Twenty Dollars and Eighty Three Cents ($20.83) per month for PLLC's use of the Lockers.

(iv) The Lease Fees, including any holdover fee for use beyond the scheduled Block Time, shall be payable within fifteen (15) days following the end of each month for the Premises, Equipment, etc. provided during the immediately preceding month. Payment for any partial month shall be prorated.

(b) No Reduction in Lease Fees. Except as otherwise expressly provided herein, the amounts payable to Hospital under this Agreement shall not be affected by reason of any defect in or damage to or loss or destruction of all or part of the Equipment from any cause whatsoever, or by interference with PLLC's use of the Equipment by any persons, or for any other reason whatsoever.

(c) Fair Market Value Adjustments. Hospital shall conduct a fair market value analysis of the Lease Fee after the second anniversary of the Commencement Date, and every two years thereafter, and will increase or reduce the Lease Fee after completion of such analysis if necessary to reflect a change in fair market value of the Premises and Equipment, as applicable. Such analysis shall be conducted by a qualified appraiser, the cost of which shall be borne by the Hospital. If PLLC objects to Hospital's valuation of the Lease Fee, then PLLC may, at its own cost, retain a qualified appraiser to conduct a fair market value analysis of the Lease Fee. If the Appraiser retained by PLLC disagrees with the fair market value determination made by the appraiser retained by the Hospital, then the Hospital's appraiser and PLLC's appraiser shall meet to resolve their differences and mutually agree upon the fair market Lease Fee to be charged to PLLC, and such agreed to amount shall be binding on the parties. Any such change to the Lease Fee shall become effective by a written amendment signed by both parties.

4. PLLC's Representations, Warranties and Covenants. PLLC hereby makes the following representations, warranties and covenants to Hospital, each of which is material and is being relied upon by Hospital, and each of which shall be true as of the date hereof and shall continue to be true throughout the Term of this Agreement:

(a) PLLC's Organizational Status. PLLC is a duly organized and validly existing professional limited liability company authorized under the laws of the State of Tennessee to engage in the practice of medicine.

(b) Authorization. The execution and delivery of this Agreement, and the performance of this Agreement by PLLC, have been duly authorized by all necessary action by PLLC, and this Agreement is legally valid and binding against PLLC in accordance with the terms hereof.

(c) Information from PLLC. Any and all factual information furnished or to be furnished by PLLC to Hospital, including, but not limited to, any reports, shall, to the best knowledge of PLLC, be true and accurate in all material respects as of the date on which such information is furnished.

(d) Compliance with Regulation. PLLC shall comply with all applicable regulations and laws in the performance of the MRI Services and its obligations hereunder, and shall do everything in its power to ensure that the conduct of the MRI Services at the Premises is in compliance with the rules of any accrediting or regulatory body, agency or authority having jurisdiction over PLLC. PLLC represents and warrants that it has reviewed all relevant federal and state health care fraud and abuse laws including, without limitation, the federal "Stark" law, and that it is, to the best of its knowledge, and shall remain throughout the Term of this Agreement, fully compliant with all of the relevant requirements of such laws as they may be amended from time to time.

(e) Notification to Patients. PLLC covenants to clearly notify its patients that the MRI Services rendered by PLLC pursuant to this Agreement are done so on PLLC's own behalf and are not rendered by, associated with or otherwise the responsibility of Hospital.

5. Hospital's Representations, Warranties and Covenants. Hospital hereby makes the following representations, warranties, and covenants to PLLC, each of which is material and is being relied upon by PLLC, and each of which shall be true as of the date hereof:

(a) Hospital's Corporate Status. Hospital is a nonprofit corporation duly organized and validly existing under the laws of the State of Tennessee.

(b) Authorization. The execution and delivery of this Agreement, and the performance of this Agreement by Hospital, have been duly authorized by all necessary action by Hospital, and this Agreement is legally valid and binding against Hospital in accordance with the terms hereof.

(c) Information from Hospital. Any and all factual information furnished or to be furnished by Hospital to PLLC, including, but not limited to, any reports, shall, to the best knowledge of Hospital, be true and accurate in all material respects as of the date on which such information is furnished.

6. Insurance. PLLC shall obtain and maintain, at its own expense, professional liability insurance (including malpractice insurance) for itself and for each of its physician employees and contractors, in the minimum amount of One Million Dollars ($1,000,000) for each occurrence and Three Million Dollars ($3,000,000) in the aggregate. PLLC shall also obtain and maintain, at its own expense, professional liability insurance (including malpractice insurance) for the Technicians who provide services hereunder in the amount of standard policy limits for similar MRI technicians. PLLC shall also keep the Equipment insured against all risks of loss or damage caused by PLLC, for not less than the aggregate amount of the total purchase price for the full value of all such Equipment and shall carry liability insurance, both personal injury and property damage, covering the Equipment. Any such insurance covering the Equipment shall be in form and amount and with companies satisfactory to Hospital and shall include the Hospital as an additional insured. Upon the Hospital's reasonable request, PLLC shall show evidence of the existence of the insurance coverage required under this Section 6.

7. Early Termination.

(a) By Hospital for Default by PLLC or Other Events. Hospital may immediately terminate this Agreement upon the occurrence of any one of the following events by sending written notice of termination to PLLC:

(i) PLLC fails to pay the Lease Fees when due and fails to cure such default within fifteen (15) days after Hospital sends written notice of default to PLLC;

(ii) PLLC attempts to or actually does remove, sell, transfer, encumber, sublicense or part with possession of the Equipment, or vacates or abandons the Premises, except as otherwise provided in this Agreement;

(iii) PLLC fails to observe or perform any of its other obligations hereunder in any material respect and such failure continues uncured for a period of thirty (30) days after Hospital sends written notice thereof to PLLC or, if such failure cannot be cured within such 30-day period, PLLC fails to commence to cure such breach within such 30-day period and/or fails to diligently proceed to effect such cure;

(iv) PLLC: (A) makes an assignment for the benefit of creditors; (B) admits in writing to its inability to pay its debts as they become due; (C) files an answer admitting the material allegations of such a petition filed against it in any such

proceeding; or (D) consents to or acquiesces in the appointment of a trustee, receiver or liquidator of all or any substantial part of its assets or properties;

(v) Any final action by any body having jurisdiction results in the termination of PLLC as a professional entity or the suspension of its charter;

(vi) Any proceedings are commenced against PLLC seeking reorganization or similar relief under any present or future statute, law or regulation and such proceedings are not dismissed within sixty (60) days, or any trustee, receiver or liquidator is appointed (without PLLC's consent or acquiescence) for all or any substantial part of PLLC's assets or properties and such appointment is not vacated within sixty (60) days;

(vii) PLLC is finally determined, by an appropriate governing body or court, to have violated any applicable law, rule, regulation or ethical standard arising out of the conduct of its private medical practice at the Premises;

(viii) There is a change in ownership of fifty percent (50%) or more of PLLC, except such changes arising from transfers by the holder of such interests to an entity controlled by, in control of or under common control with such transferor; or

(ix) Hospital ceases, at its option, to provide MRI Services at the Premises.

(b) Termination By Hospital Upon Creation of Substantial Risk. In the event Hospital receives advice from legal counsel that any of the transactions contemplated by this Agreement creates, or has created, a substantial risk of: (i) jeopardizing the tax-exempt status of Hospital or Hospital's parent organization under Section 501(c)(3) of the Internal Revenue Code; (ii) subjecting Hospital or Hospital's parent organization to an excise tax under Section 4958 of the Internal Revenue Code; (iii) violating federal or state anti-fraud and abuse laws, including, but not limited to, 42 U.S.C. §1320a-7b; or (iv) violating federal or state prohibitions on physician self-referral, including, but not limited to, 42 U.S.C. §1395nn; or in the event Hospital determines that any law, statute, rule, regulation, third-party payor policy or other requirement, existing at the time of execution of this Agreement, or as adopted or amended subsequent thereto, shall cause any paragraph or provision of this Agreement to be invalid, void or in any manner unlawful or subject either party to penalty, or prohibits, restricts or substantially alters reimbursement for services performed hereunder, then the parties agree that if the risk can be eliminated by restructuring the Agreement, this Agreement shall be renegotiated in good faith so as to restructure their relationship in a manner that would eliminate any such substantial risk. In the event the parties are unable to so successfully renegotiate this Agreement or Hospital, in its discretion, determines the risk cannot be eliminated by renegotiation, then Hospital shall be entitled to terminate this Agreement upon the giving of twenty-one (21) days' written notice to PLLC.

(c) By Either Party. Either party may terminate this Agreement without cause, at any time by sending one hundred and eighty (180) days' prior written notice to the other party, which notice shall state the effective date of such termination; provided, however, that in the event this Agreement is terminated pursuant to this Section 7(c), the parties shall not enter into a new agreement for the same or substantially similar services until the initial one-year contract period has lapsed.

8. Independent Contractor. This Agreement is not intended, and shall not be construed, to create a venture, partnership or association as between Hospital and PLLC. Each party is an independent contractor of the other.

9. Alterations. PLLC shall not make or permit any repairs, augmentation, changes or alterations to the Equipment or the Premises, nor remove the Equipment from the Premises without the prior written consent of Hospital, which approval may be granted or withheld in Hospital's sole discretion. The costs of such alterations or upgrades shall be promptly reimbursed by Hospital to PLLC. All accessories, replacements, parts and substitutions for, or which are added or attached to, the Equipment shall become the property of Hospital and be within the definition hereunder of the Equipment, and shall be subject to this Agreement.

10. Compliance with Federal Anti-Kickback and Physician Self-Referral Statutes. Notwithstanding any unanticipated effect of any of the provisions herein, no party intends to violate the federal Anti-Kickback Statute and/or the federal Physician Self-Referral Statute, as such provisions are amended from time to time. Accordingly, the parties acknowledge that there is no obligation of PLLC to refer patients to the Hospital or to any health care provider affiliated with the Hospital, nor any intent to influence the judgment of PLLC regarding where their patients receive health care services. In addition, there is no obligation of the Hospital to refer or influence the referral of patients to PLLC. The parties intend that this Agreement meet the requirements of: (i) the space and equipment rental safe harbors to the federal Anti-Kickback Statute which are set forth in 42 CFR Part 1001.952 (b) and (c), and (ii) the office space and equipment rental exceptions and/or the physician payment for services and items exception to the federal Physician Self-Referral Statute which are set forth in 42 U.S.C. Section 1395nn(e)(1) and (8), and the corresponding regulations, the fair market value compensation exception to the Physician Self-Referral Statute which is set forth in 42 C.F.R. Section 411.357(l), or the indirect compensation arrangements exception to the Physician Self-Referral Statute which is set forth in 42 C.F.R. Section 411.357(p). The consideration paid to Hospital hereunder is fair market value based upon arm's length bargaining and consistent with amounts paid for similar items and services. The consideration paid hereunder is intended solely as compensation to Hospital for the items and services described herein. Neither party intends to influence the judgment of the other party or any of such party's employees or agents regarding where their patients receive health care services.

11. Complete and Entire Agreement. This Agreement, including the attached Exhibits, constitutes the entire agreement between the parties with respect to the subjects covered herein and there are no representations, warranties or prior understandings except as expressly set forth herein.

12. Compliance with HIPAA. Each party warrants to the other party that it is a covered entity as defined under the Health Insurance Portability and Accountability Act of 1996 and the final regulations promulgated thereunder, as they may be amended from time to time, including through the Health Information Technology for Economic and Clinical Health Act (collectively, "HIPAA"). With respect to its performance of this Agreement, each party shall at all times comply, and shall cause its employees and contractors to comply, with the patient information, privacy and security provisions of HIPAA. In the event either party discloses, or provides access to, its protected health information (as defined under HIPAA) to the other party or to the employees or contractors of the other party, such other party shall at all times comply, and shall cause its employees or contractors who have access to such protected health information to comply, with the HIPAA policies of the party that owns the patient information.

13. Confidentiality. The parties shall not disclose any secrets or confidential information, proprietary information, patient lists or trade secrets of the other party, or any matter or thing ascertained by the parties through their association under this Agreement, the use or disclosure of which might be reasonably construed to be contrary to the best interest of the other party. The parties further agree that should this Agreement terminate, neither will take nor retain any papers, records, files, computer programs or software, patient lists, or patient medical billings or files, other document or copies thereof (except as provided for in other sections of this Agreement), or other confidential information of any kind belonging to the other. Without limiting other possible remedies of the parties for the breach of this covenant, both agree that injunctive relief or other relief shall be available to either party to enforce this covenant, such relief to be without the necessity of posting a bond. Hospital shall not be deemed to violate this Section 13 to the extent it discloses any such information to any permissible entity to which Hospital assigns this Agreement pursuant to the terms of Section 16 below.

14. Restrictive Covenant. During the Term of this Agreement, and if this Agreement Terminates for any reason prior to expiration of the Term, except for a termination by Hospital pursuant to Sections 7(a)(ix), 7(b), or 7(c), then for a period of two (2) years after any such early termination of this Agreement, PLLC shall not in any way:

(a) On its own or in concert with others, own, operate, manage, lend money to, provide services to, or otherwise have a financial relationship with any business that is competitive with the Hospital's MRI Services and is located within the Restricted Area;

(b) Enter into any agreement to engage in any of the activities described in Section 14(a).

For purposes of this Section 14, "Restricted Area" shall mean Carter, Washington and Unicoi Counties, Tennessee. PLLC's provision of MRI Services to its own patients pursuant to this Agreement, including any related professional services, shall not be considered competition with Hospital's MRI services. The parties have carefully read and considered the provisions of this Section 14 and, having done so, agree that monetary damages alone will be inadequate to protect the Hospital in the event of a breach or threatened breach or violation of the restrictive covenants contained herein. Therefore, in the event of such a breach or threatened breach of such restrictive covenants by PLLC, the Hospital shall be entitled to a restraining order, if necessary, and an injunction restraining such breach or threatened breach. Such injunctive remedy shall not be in limitation of, but in addition to, any other remedies authorized at law for the breach or threatened breach of such restrictive covenants, including the recovery of monetary damages.

15. Indemnification. PLLC agrees to indemnify, defend and hold harmless Hospital, its directors, officers, agents and employees from any and all liabilities, claims (whether accrued, absolute, contingent or otherwise), losses, actions, demands, liabilities, fines, penalties, damages, expenses (including reasonable attorneys' fees) or deficiencies (collectively, "Claims") occurring or resulting from (i) any act of malpractice or professional negligence by PLLC, its Technicians, physicians, employees, contractors or agents, (ii) any negligent acts or omissions by PLLC, its Technicians, physicians, employees, contractors or agents, related to the operation of the Equipment, and/or (iii) any breach of a covenant or representation made by PLLC hereunder. PLLC shall promptly notify Hospital of any such Claim made against PLLC. The provisions of this Section 15 shall survive the termination of this Agreement.

16. Assignments. This Agreement may not be assigned by PLLC without the prior written consent of Hospital, which consent may be granted or withheld in Hospital's sole discretion. Any attempt

to make any assignment in violation of the provisions hereof shall be null and void. Hospital may assign its interests hereunder to any entity under common ownership or control without consent of or notice to PLLC.

17. Force Majeure. If either party's ability to perform its obligations hereunder is limited or prevented in whole or in part due to acts of God, war, invasion, acts of foreign enemy, hostilities (whether war be declared or not), strikes and/or industrial disputes, delay on the part of the supplier or transportation delay, such party, without liability of any kind, shall be excused, discharged and released from performance to the extent such performance is limited, delayed or prevented.

18. Waiver of Breach. No waiver of a breach of any provision of this Agreement shall be construed to be a waiver of any breach of any other provisions of this Agreement or of any succeeding breach of any provision of this Agreement.

19. Amendment of Agreement. This Agreement shall not be altered or amended except pursuant to any instrument or writing signed by the party against whom enforcement is sought.

20. Notices. All notices permitted or required under this Agreement shall be sent by Federal Express, Express Mail or by certified U.S. mail deposited with the post office, return receipt requested, postage pre-paid, and shall be deemed to have been given two (2) days from the date so deposited with the courier or U.S. mail service. Notices shall be sent to the parties as follows:

If to PLLC, a copy shall be sent to:

Medical Care, PLLC
Attn: Steve Hopland, CEO
1500 West Elk Avenue
Elizabethton, Tennessee 37643

If to Hospital, a copy shall be sent to:

Mountain States Health Alliance
d/b/a Sycamore Shoals Hospital
Attn: Hospital Administrator
1501 West Elk Avenue
Elizabethton, Tennessee 37643

Any person to whom notice or copies of notices may be given hereunder may from time to time change said address by written notice to the others as provided herein.

21. Miscellaneous.

(a) Governing Law. This Agreement and the rights of the parties hereunder shall be governed by and interpreted in accordance with the laws of the State of Tennessee without giving effect to conflicts of laws principles.

(b) Binding Effect. Except as herein otherwise specifically provided, this Agreement shall be binding upon and inure to the benefit of Hospital, PLLC and their respective legal representatives, administrators, successors and permitted assigns.

(c) Captions. Captions contained in this Agreement are inserted only as a matter of convenience and in no way define, limit or extend the scope or intent of this Agreement or any provision hereof.

(d) Counterparts. This Agreement may be executed in several counterparts, and all so executed shall constitute one agreement, binding on all parties hereto.

(e) Attorneys' Fees. In the event that either party must engage legal counsel to undertake litigation or arbitration to enforce its rights hereunder, each party in such legal proceeding or arbitration, as the case may be, shall pay its own attorneys' fees and other costs of enforcement.

(f) Severability. Whenever possible, each provision of this Agreement shall be interpreted in such a manner as to be effective and valid under applicable law. However, if any provision of this Agreement shall be prohibited by or invalid under such law, it shall be deemed modified to conform to the minimum requirements of such law or, if for any reason it is not deemed so modified, it shall be prohibited or invalid only to the extent of such prohibition or invalidity without the remainder thereof or any other such provision being prohibited or invalid.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day, month and year first above written.

PLLC: MEDICAL CARE, PLLC

By: _____

Printed or Typed Name: Steven Hopkins

Title: CEO

Hospital: MOUNTAIN STATES HEALTH ALLIANCE d/b/a SYCAMORE SHOALS HOSPITAL

By: _____

Printed or Typed Name: Dwayne Taylor

Title: CEO

APPROVED BY MSHA LEGAL DEPARTMENT

EXHIBITS

1.	Premises	Exhibit A
2.	Equipment	Exhibit B
3.	Schedule of Use	Exhibit C

Exhibit A

Floor Plan of the Premises

See Attached.

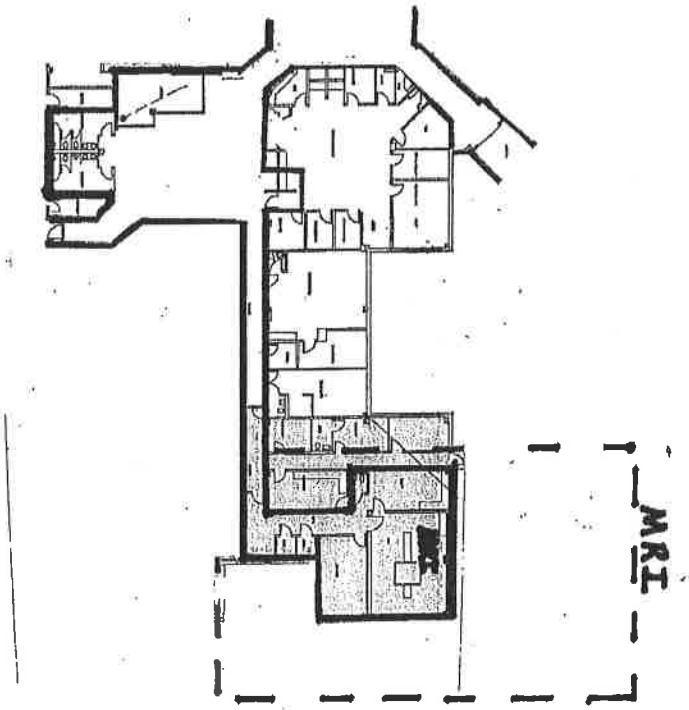


Exhibit B

Equipment

MRI Unit:
General Electric 1.5T Signa, 4-channel, short bore

New MRI Unit:
Toshiba Titan 1.5T, 16-channel, short bore

Mobile MRI

Description of the Mobile MRI will be attached on **Exhibit B-1** when known.

Exhibit C

Schedule of Use

- Tuesdays from 7:00am until 11:00am
- Tuesdays from 11:30am until 3:30pm
- Fridays from 7:00am until 11:00am

AMENDMENT TO MRI LICENSE AGREEMENT

THIS AMENDMENT is made and entered into this the 10th day of December, 2014 (the "Effective Date"), by and between by and between **MOUNTAIN STATES HEALTH ALLIANCE D/B/A SYCAMORE SHOALS HOSPITAL** ("Hospital") and **MEDICAL CARE, PLLC** ("PLLC").

WHEREAS, the parties entered into an MRI License Agreement effective December 1, 2014, pursuant to which Hospital agreed to provide to PLLC certain space and medical equipment to assist PLLC in providing MRI Services to its patients; and

WHEREAS, PLLC recently learned that it will be required to obtain a certificate of need ("CON") to provide the MRI Services to its patients pursuant to the Agreement;

NOW THEREFORE, the parties agree as follows:

1. All terms capitalized in this Amendment and not defined herein shall have the same meaning as set forth in the Agreement.

2. Commencing on the Effective Date, the license granted to PLLC pursuant to the Agreement shall be suspended until such time as PLLC obtains a CON. The license shall be reinstated on the first Tuesday or Friday occurring after the date the CON is granted (the "Reinstatement Date").

3. The parties agree that PLLC will pay the fees due under Section 3(a)(i) of the Agreement for the following dates: December 2, 2014, December 5, 2014 and December 9, 2014. PLLC will also pay a pro rata portion of the fee due under Section 3(a)(iii) for the period December 1, 2014 through December 9, 2014. The Lease Fees shall resume on the Reinstatement Date.

4. All other terms and conditions of the original Agreement, not amended herein, shall remain valid and binding upon the parties hereto.

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed as of the day and year first above written.

"Hospital"

MOUNTAIN STATES HEALTH ALLIANCE D/B/A SYCAMORE SHOALS HOSPITAL

By: _____
Dwayne Taylor, CEO

"PLLC"

MEDICAL CARE, PLLC

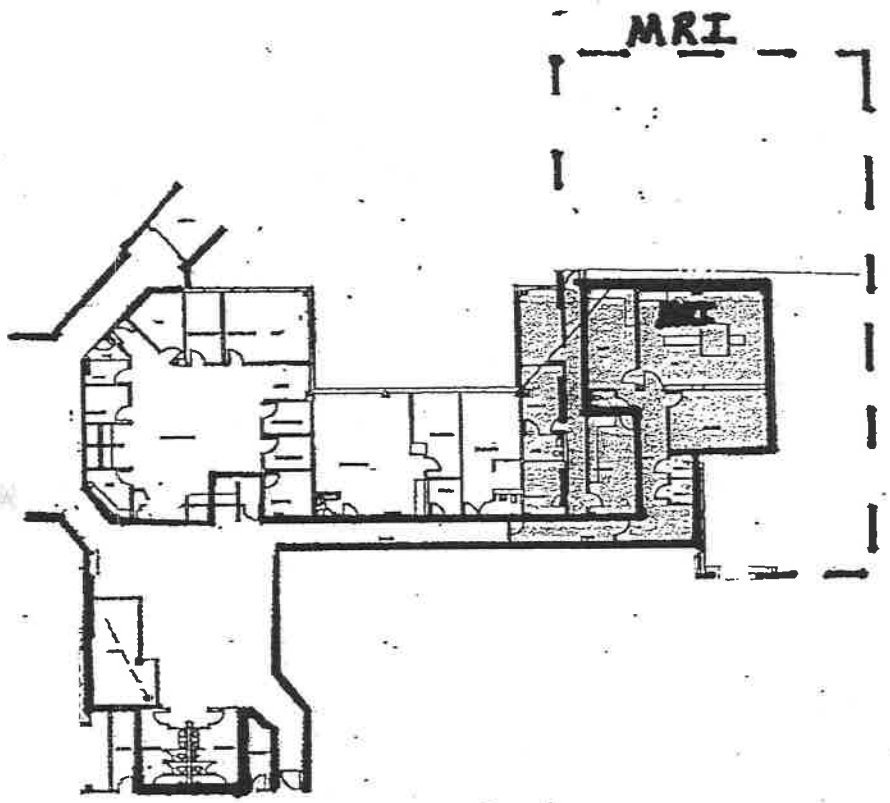
By: _____

Name: Steven Hapland

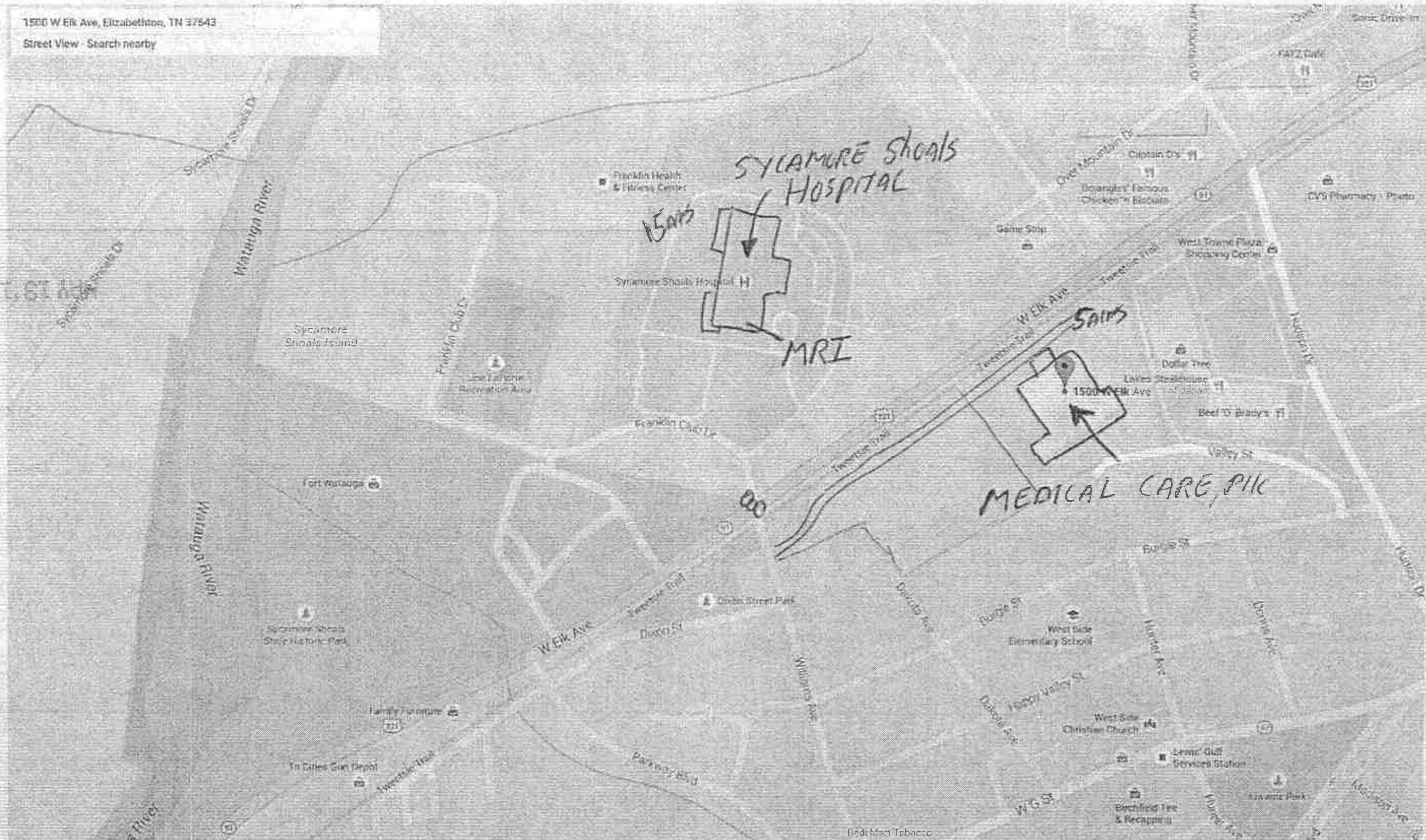
Title: CEO

S:\Public\legal\RQK\Contracts\Medical Care SSH Amendment.doc

Attachment B, IV.


MRI

Attachment B, III.


1500 W Elk Ave, Elizabethton, TN 37643
Street View · Search nearby
SYCAMORE Shoals HOSPITAL
15 MIN
MRI
5 MIN
MEDICAL CARE, PLLC
Sycamore Shoals Hospital
Franklin Health & Fitness Center
Watauga River
Sycamore Shoals Island
Franklin Club Dr
Fort Watauga
Sycamore Shoals State Historic Park
W Elk Ave
Tweetsie Trail
Family Furniture
Tri Cities Gun Depot
Parkway Blvd
Dixon Street Park
Williams Ave
Dakota Ave
Burgie St
West Side Elementary School
Happy Valley St
West Side Christian Church
Hunter Ave
Dennis Ave
Lewis' Gulf Services Station
Birchfield Tire & Recapping
W G St
Valley St
Dollar Tree
1500 W Elk Ave
Beef 'O' Brady's
Game Stop
West Towne Plaza Shopping Center
Captain D's
Bojangles' Famous Chicken 'n Biscuits
Over Mountain Dr
CVS Pharmacy · Photo
FATZ Cafe
Sonic Drive-In
Hudson Dr
Map data ©2015 Google 200 ft

Attachment B, II, E, 4.

DEC - 2 2011

510(k) SUMMARY AND EFFECTIVENESS

1. DEVICE NAME:

Generic Name:	Magnetic Resonance Diagnostic Device
Model Name:	MRT-1504/A5
Trade/ Proprietary Name:	Vantage Titan HSR

2. ESTABLISHMENT REGISTRATION: 2020563

3. U.S AGENT INFORMATION:

U.S. Agent Name:	Paul Biggins (714) 730-5000
Establishment Name and Address:	Toshiba America Medical Systems, Inc. 2441 Michelle Drive Tustin, Ca. 92780

4. MANUFACTURING SITE: Toshiba Medical Systems Corporation
1385 Shimoishigami
Otawara-shi, Tochigi 324-8550
Japan

5. DATE OF SUBMISSION: November 14, 2011

6. DEVICE DESCRIPTION:
The Vantage Titan HSR (Model MRT-1504/A5) is a 1.5 Tesla Magnetic Resonance Imaging (MRI) System. The Vantage Titan HSR uses the same magnet as the existing Vantage Titan (K080038). It includes the Toshiba Pianissimo™ technology (scan noise reduction technology). The design of the gradient coil and the WB coil of the Vantage Titan HSR provides the maximum field of view of 55 x 55 x 55 cm.

7. SUMMARY OF MAJOR HARDWARE CHANGES
a. New Gradient amplifier
b. New Gradient coil
c. Wireless gating unit is added (optional)

8. SUMMARY OF MAJOR SOFTWARE CHANGES

a. New Software platform
b. Modified the data base for distribution correction and dB/dt calculation for new gradient coil.

9. SAFETY PARAMETERS

Item	New Vantage Titan HSR (Subject device)	EXCELART Vantage Titan , K080038 (Predicate Device)	Notes
Static field strength	1.5T	1.5T	Same
Peak and A-weighted acoustic noise	113.0 dB (A-weighted) 121.6 dB (peak)	105.7 dB (A-weighted) 115.7dB (peak)	Same
Operational Modes	1st Operating Mode	1st Operating Mode	Same
i. Safety parameter display	SAR dB/dt	SAR dB/dt	Same
ii. Operating mode access requirements	Allows screen access to 1st level operating mode	Allows screen access to 1st level operating mode	Same
Maximum SAR	4W/kg for whole body (1st operating mode specified in IEC 60601-2-33(2002))	4W/kg for whole body (1st operating mode specified in IEC 60601-2-33(2002))	Same
Maximum dB/dt	<1st operating mode specified in IEC 60601-2-33 (2002)	<1st operating mode specified in IEC 60601-2-33 (2002)	Same
Gradient coil dimensions	760 x 893 x 1405 (inner diameter x outer diameter x length, unit = mm)	760 x 893 x 1405 (inner diameter x outer diameter x length, unit = mm)	Same
Potential emergency condition and means provided for shutdown	Shut down by Emergency Ramp Down Unit for collision hazard for ferromagnetic objects	Shut down by Emergency Ramp Down Unit for collision hazard for ferromagnetic objects	Same
Biocompatibility of materials	Confirmed for electrodes and accessories for wireless gating	Not applicable	

10. IMAGING PERFORMACE PARAMETERS

No change from the previous predicate submission (K080038).

11. INTEDED USE

The MRI system is indicated for use as a diagnostic imaging modality that produces cross-sectional transaxial, coronal, sagittal, and oblique images that display anatomic structures of the head or body. In addition, this system supports non-contrast MRA.

MRI (magnetic resonance imaging) images correspond to the spatial distribution of protons (hydrogen nuclei) that exhibit nuclear magnetic resonance (NMR). The NMR properties of body tissues and fluids are:

- Proton density (PD) (also called hydrogen density)
- Spin-lattice relaxation time (T1)
- Spin-spin relaxation time (T2)
- Flow dynamics
- Chemical shift

Contrast agent use is restricted to the approved drug indications. When interpreted by a trained physician, these images yield information that can be useful in diagnosis.

12. DESIGN CHANGE

The Vantage Titan HSR MRI System is comparable to the existing 1.5T Vantage Titan MRI System (K080038), with the following modifications.

a. Maximum gradient slew rate has been changed.
b. Power requirements have been changed.
c. CPU platform has been changed.

13. SUMMARY OF DESIGN CONTROL ACTIVITIES

PS Risk List for software and hardware of changing unit have been completed and are attached. The test methods used are the same as those submitted in the previously cleared submissions (K0800338). A declaration of conformity with design controls is included in this submission.

14. TRUTHFUL AND ACCURACY CERTIFICATION

A certification of the truthfulness and accuracy of the Vantage Titan HSR described in this submission is provided in this submission.

15. SUBSTANTIAL EQUIVALENCE

Toshiba Medical Systems Corporation believes that the Vantage Titan HSR (model MRT-1504/A5) Magnetic Resonance Imaging (MRI) System is substantially equivalent to the previously cleared predicate devices referenced in this submission.

Testing was done in accordance with applicable recognized consensus standards as listed below. Additionally, human volunteer studies (in Japan) were conducted to verify imaging performance.

List of Applicable Standards

- IEC60601-1:1988, Amd.1:1991, Amd.2:1995
- IEC60601-1-1:2000
- IEC60601-1-2:2001, Amd.1:2004
- IEC60601-1-4:1996, Amd.1:1999
- IEC60601-1-6:2004
- IEC60601-1-8:2003,Amd.1:2006
- IEC60601-2-33:2002, Amd.1:2005, Amd.2:2007
- IEC60825-1: 2007
- IEC62304:2006
- IEC62366:2007
- NEMA MS-1:2008
- NEMA MS-2:2003
- NEMA MS-3:2008
- NEMA MS-4:2006
- NEMA MS-5:2003
- NEMA PS 3.1-18 (2008)

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Toshiba Medical Systems Corporation
Mr. Paul Biggins
Director Regulatory Affairs/U.S. Agent
% Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

DEC - 2 2011

Re: K112003
Trade/Device Name: MRT-1504/A5, Vantage Titan HSR
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: November 14, 2011
Received: November 15, 2011

Dear Mr. Biggins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K112003

Indications for Use

510(k) Number (if known): K112003

Device Name: MRT-1504/A5, Vantage Titan HSR

Indications for Use:

The MRI system is indicated for use as a diagnostic imaging modality that produces cross-sectional transaxial, coronal, sagittal, and oblique images that display anatomic structures of the head or body. In addition, this system supports non-contrast MRA.

MRI (magnetic resonance imaging) images correspond to the spatial distribution of protons (hydrogen nuclei) that exhibit nuclear magnetic resonance (NMR). The NMR properties of body tissues and fluids are:

- Proton density (PD) (also called hydrogen density)
- Spin-lattice relaxation time (T1)
- Spin-spin relaxation time (T2)
- Flow dynamics
- Chemical shift

Contrast agent use is restricted to the approved drug indications. When interpreted by a trained physician, these images yield information that can be useful in diagnosis.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K112003

Attachment B, II, E, 3.

CPT	MRI	Medical Care, PLLC Gross Charge	Medicare Physician Fee Schedule
70551	MRI HEAD W/O CONTRAST	$1,400.00	437.20
70552	MRI HEAD W/ CONTRAST	$1,640.00	488.23
70553	MRI HEAD W/ & W/O CONTRAST	$2,060.00	571.93
71550	MRI CHEST W/O CONTRAST	$1,400.00	477.68
71551	MRI CHEST W CONTRAST	$1,640.00	530.76
71552	MRI CHEST W & W/O CONTRAST	$2,200.00	675.02
72141	MRI CERVICAL SPINE W/O CONTRAST	$1,250.00	387.18
72142	MRI CERVICAL SPINE W/ CONTRAST	$1,500.00	498.10
72146	MRI THORACIC SPINE W/O CONTRAST	$1,400.00	387.86
72147	MRI THORACIC SPINE W/ CONTRAST	$1,500.00	439.92
72148	MRI LUMBAR SPINE W/O CONTRAST	$1,300.00	382.08
72149	MRI LUMBAR SPINE W/ CONTRAST	$1,600.00	481.43
72156	MRI C SPINE W/ & W/O CONTRAST	$2,000.00	572.27
72157	MRI T SPINE W/ & W/O CONTRAST	$2,000.00	531.78
72158	MRI L SPINE W/ & W/O CONTRAST	$2,000.00	560.02
72195	MRI PELVIS W/O CONTRAST	$1,250.00	432.09
72196	MRI PELVIS W CONTRAST	$1,500.00	480.06
72197	MRI PELVIS W & W/O CONTRAST	$1,900.00	585.88
73218	MRI UPPER EXTREMITY W/O CONTRAST	$1,200.00	424.95
73219	MRI UPPER EXTREMITY W CONTRAST	$1,450.00	471.56
73220	MRI UPPER EXTREMITY W & W/O CONTRAST	$1,750.00	581.45
73221	MRI UPPER EXTREMITY JOINT W/O CONTRAST	$1,200.00	282.05
73222	MRI UPPER EXTREMITY JOINT W CONTRAST	$1,400.00	442.64
73223	MRI UPPER EXTREMITY JOINT W & W/O CONTRAST	$1,900.00	548.11
73718	MRI LOWER EXTREMITY W/O CONTRAST	$1,200.00	422.23
73719	MRI LOWER EXTREMITY W CONTRAST	$1,400.00	479.38
73720	MRI LOWER EXTREMITY W & W/O CONTRAST	$1,750.00	585.20
73721	MRI LOWER EXTREMITY JOINT W/O CONTRAST	$1,200.00	282.05
73722	MRI LOWER EXTREMITY JOINT W CONTRAST	$1,350.00	449.10
73723	MRI LOWER EXTREMITY JOINT W & W/O CONTRAST	$1,950.00	547.77
74181	MRI ABDOMEN W/O CONTRAST	$1,400.00	382.42
74182	MRI ABDOMEN W CONTRAST	$1,600.00	528.04
74183	MRI ABDOMEN W & W/O CONTRAST	$2,000.00	587.92
MEDICAL CARE, PLLC AVERAGE GROSS CHARGE PER PROCEDURE		$1,584.55	

Attachment C, I, Need a.1.a.

Health Care Providers that Utilize MRI's - Utilization *(As of 8/11/2014)*

County	Provider Type	Provider	Year	Number of	Mobile?	MobileDays	Total Procedures	Total Gross Charges
Cannon	HOSP	Stones River Hospital	2011	1	Fixed	0	576	$928,458.58
Cannon	HOSP	Stones River Hospital	2012	1	Fixed	0	451	$848,942.00
Cannon	HOSP	Stones River Hospital	2013	1	Fixed	0	379	$754,433.00
Carroll	HOSP	Baptist Memorial Hospital - Huntingdon	2011	1	Fixed	0	1119	$2,352,481.00
Carroll	HOSP	Baptist Memorial Hospital - Huntingdon	2012	1	Fixed	0	986	$2,322,890.00
Carroll	HOSP	Baptist Memorial Hospital - Huntingdon	2013	1	Fixed	0	909	$2,420,972.00
Carroll	ODC	McKenzie Medical Center	2011	1	Fixed	0	1840	$0.00
Carroll	ODC	McKenzie Medical Center	2012	1	Fixed	0	2279	$3,311,455.00
Carroll	ODC	McKenzie Medical Center	2013	1	Fixed	0	1681	$2,383,682.00
Carroll	HOSP	McKenzie Regional Hospital	2011	1	Mobile (Part)	1 day/week	87	$430,865.00
Carroll	HOSP	McKenzie Regional Hospital	2012	1	Mobile (Part)	1 day/week	79	$430,437.53
Carroll	HOSP	McKenzie Regional Hospital	2013	1	Mobile (Part)	1 day/week	25	$137,367.00
Carter	HOSP	Sycamore Shoals Hospital	2011	1	Fixed	0	1958	$7,394,861.00
Carter	HOSP	Sycamore Shoals Hospital	2012	1	Fixed	0	2014	$8,254,830.00
Carter	HOSP	Sycamore Shoals Hospital	2013	1	Fixed	0	1719	$7,505,749.00
Cheatham	HOSP	TriStar Ashland City Medical Center	2011	1	Mobile (Part)	2 days/week	322	$1,340,542.00
Cheatham	HOSP	TriStar Ashland City Medical Center	2012	1	Mobile (Part)	2 days/week	375	$1,667,488.00
Cheatham	HOSP	TriStar Ashland City Medical Center	2013	1	Mobile (Part)	2 days/week	303	$1,515,918.00
Chester	PO	Frix Jennings Clinic, PC	2011	1	Mobile (Part)	4 half days/week	667	$773,230.00
Chester	PO	Frix Jennings Clinic, PC	2012	1	Mobile (Part)	4 half days/week	637	$762,810.00
Chester	PO	Frix Jennings Clinic, PC	2013	1	Mobile (Part)	4 half days/week	715	$843,450.00
Claiborne	HOSP	Claiborne County Hospital	2011	1	Fixed	0	8168	$2,747,743.00
Claiborne	HOSP	Claiborne County Hospital	2012	1	Fixed	0	1642	$3,496,233.00
Claiborne	HOSP	Claiborne County Hospital	2013	1	Fixed	0	1436	$3,218,298.00
Cocke	HOSP	Newport Medical Center	2011	1	Fixed	0	1519	$4,544,646.00
Cocke	HOSP	Newport Medical Center	2012	1	Fixed	0	1255	$0.00
Cocke	HOSP	Newport Medical Center	2013	1	Fixed	0	1274	$0.00
Coffee	HOSP	Harton Regional Medical Center (John W.)	2011	1	Fixed	0	2506	$6,597,077.00
Coffee	HOSP	Harton Regional Medical Center (John W.)	2011	1	Mobile (Full)	5 days/week	477	$1,441,955.00
Coffee	HOSP	Harton Regional Medical Center (John W.)	2012	1	Mobile (Full)	5 days/week	2746	$8,954,779.00
Coffee	HOSP	Harton Regional Medical Center (John W.)	2013	1	Fixed	0	2538	$8,484,102.00
Coffee	HOSP	Medical Center of Manchester	2011	1	Mobile (Part)	2 days/week	671	$950,772.00
Coffee	HOSP	Medical Center of Manchester	2012	1	Fixed	0	705	$1,390,701.92
Coffee	HOSP	Medical Center of Manchester	2013	1	Fixed	0	632	$1,309,206.00
Coffee	HOSP	United Regional Medical Center	2011	1	Fixed	0	2020	$3,370,928.00
Coffee	HOSP	United Regional Medical Center	2012	1	Fixed	0	2107	$3,520,349.00
Coffee	HOSP	United Regional Medical Center	2013	1	Fixed	0	1615	$2,713,460.00
Cumberland	HOSP	Cumberland Medical Center, Inc.	2011	2	Fixed	0	4266	$10,346,246.00
Cumberland	HOSP	Cumberland Medical Center, Inc.	2012	2	Fixed	0	4979	$14,327,560.00

Health Care Providers that Utilize MRI's - Utilization *(As of 8/11/2014)*

County	Provider Type	Provider	Year	Number of	Mobile?	MobileDays	Total Procedures	Total Gross Charges
Hardin	HOSP	Hardin Medical Center	2013	1	Fixed	0	1470	$3,108,230.00
Hawkins	HOSP	Hawkins County Memorial Hospital	2011	1	Mobile (Part)	3 days/week	1065	$2,463,274.00
Hawkins	HOSP	Hawkins County Memorial Hospital	2012	1	Mobile (Part)	3 days/week	895	$2,188,838.00
Hawkins	HOSP	Hawkins County Memorial Hospital	2013	1	Mobile (Part)	3 days/week	877	$2,318,663.00
Haywood	HOSP	Haywood Park Community Hospital	2011	1	Mobile (Part)	1 day/week	222	$1,042,564.00
Haywood	HOSP	Haywood Park Community Hospital	2012	1	Mobile (Part)	1 day/week	206	$1,036,357.00
Haywood	HOSP	Haywood Park Community Hospital	2013	1	Mobile (Part)	1 day/week	179	$966,465.00
Henderson	HOSP	Henderson County Community Hospital	2011	1	Mobile (Part)	3 days/week	474	$1,987,358.00
Henderson	HOSP	Henderson County Community Hospital	2012	1	Mobile (Part)	3 days/week	504	$2,277,682.00
Henderson	HOSP	Henderson County Community Hospital	2013	1	Mobile (Part)	3 days/week	411	$1,979,283.00
Henry	HOSP	Henry County Medical Center	2011	1	Fixed	0	1077	$2,249,266.00
Henry	HOSP	Henry County Medical Center	2011	1	Mobile (Full)	5 days/week	1614	$3,372,978.00
Henry	HOSP	Henry County Medical Center	2012	2	Fixed	0	1168	$2,607,001.00
Henry	HOSP	Henry County Medical Center	2012	1	Mobile (Full)	7 days/week	1750	$3,910,501.00
Henry	HOSP	Henry County Medical Center	2013	2	Fixed	0	3257	$7,449,806.00
Hickman	HOSP	St. Thomas Hickman Hospital	2011	1	Mobile (Part)	1 day/week	147	$361,494.00
Hickman	HOSP	St. Thomas Hickman Hospital	2012	1	Mobile (Part)	1 day/week	214	$622,909.00
Hickman	HOSP	St. Thomas Hickman Hospital	2013	1	Mobile (Part)	1 day/week	247	$618,107.00
Houston	HOSP	Houston County Community Hospital	2011	1	Mobile (Part)	1 day/week	191	$236,700.00
Houston	HOSP	Houston County Community Hospital	2012	1	Mobile (Part)	1 day/week	223	$0.00
Houston	HOSP	Houston County Community Hospital	2013	1	Mobile (Part)	1 day/week	74	$87,138.00
Jefferson	HOSP	Jefferson Memorial Hospital	2011	1	Mobile (Full)	6 days/week	2714	$8,290,766.00
Jefferson	HOSP	Jefferson Memorial Hospital	2012	1	Mobile (Full)	6 days/week	3098	$0.00
Jefferson	HOSP	Jefferson Memorial Hospital	2013	1	Mobile (Full)	7 days/week	2074	$7,385,063.00
Johnson	HOSP	Johnson County Community Hospital	2011	1	Mobile (Part)	2 days/month	274	$994,442.00
Johnson	HOSP	Johnson County Community Hospital	2012	1	Mobile (Part)	4 days/month	308	$1,227,542.00
Johnson	HOSP	Johnson County Community Hospital	2013	1	Mobile (Part)	4 days/month	267	$950,111.00
Knox	RPO	Abercrombie Radiology	2011	2	Fixed	0	4856	$0.00
Knox	RPO	Abercrombie Radiology	2012	2	Fixed	0	4732	$0.00
Knox	RPO	Abercrombie Radiology	2013	2	Fixed	0	4313	$0.00
Knox	PO	Ancillary Services, Summit Medical Group	2011	1	Fixed	0	3320	$3,532,307.00
Knox	PO	Ancillary Services, Summit Medical Group	2012	1	Fixed	0	3021	$3,266,346.00
Knox	PO	Ancillary Services, Summit Medical Group	2013	1	Fixed	0	2768	$2,958,315.00
Knox	PO	Ancillary Svcs-Summit Medical Group-Midlake	2011	1	Fixed	0	2318	$2,456,474.00
Knox	PO	Ancillary Svcs-Summit Medical Group-Midlake	2012	1	Fixed	0	2273	$2,446,206.00
Knox	PO	Ancillary Svcs-Summit Medical Group-Midlake	2013	1	Fixed	0	2317	$2,428,637.00
Knox	HOSP	East Tennessee Children's Hospital	2011	1	Fixed	0	2524	$5,008,496.00
Knox	HOSP	East Tennessee Children's Hospital	2012	1	Fixed	0	2594	$5,262,165.00
Knox	HOSP	East Tennessee Children's Hospital	2013	1	Fixed	0	2674	$5,816,360.00

Health Care Providers that Utilize MRI's - Utilization *(As of 8/11/2014)*

County	Provider Type	Provider	Year	Number of	Mobile?	MobileDays	Total Procedures	Total Gross Charges
Shelby	H-Imaging	Park Avenue Diagnostic Center	2011	2	Fixed	0	3080	$11,856,616.00
Shelby	H-Imaging	Park Avenue Diagnostic Center	2012	2	Fixed	0	2681	$10,828,551.00
Shelby	H-Imaging	Park Avenue Diagnostic Center	2013	2	Fixed	0	2075	$9,689,500.00
Shelby	HOSP	Regional Medical Center, The (Regional One Health)	2011	1	Fixed	0	3927	$12,608,247.00
Shelby	HOSP	Regional Medical Center, The (Regional One Health)	2012	1	Fixed	0	4491	$13,925,978.00
Shelby	HOSP	Regional Medical Center, The (Regional One Health)	2013	1	Fixed	0	4131	$12,918,705.00
Shelby	PO	Semmes Murphey Clinic (Humphreys Blvd)	2011	2	Fixed	0	7300	$12,914,072.00
Shelby	PO	Semmes Murphey Clinic (Humphreys Blvd)	2012	2	Fixed	0	6490	$12,335,875.00
Shelby	PO	Semmes Murphey Clinic (Humphreys Blvd)	2013	2	Fixed	0	6277	$11,696,373.00
Shelby	HOSP	St. Francis Hospital	2011	3	Fixed	0	5482	$20,929,309.00
Shelby	HOSP	St. Francis Hospital	2012	3	Fixed	0	5393	$22,089,210.00
Shelby	HOSP	St. Francis Hospital	2013	3	Fixed	0	5326	$24,698,978.00
Shelby	HOSP	St. Francis Hospital - Bartlett	2011	2	Fixed	0	3257	$8,326,389.00
Shelby	HOSP	St. Francis Hospital - Bartlett	2012	2	Fixed	0	3642	$9,989,370.00
Shelby	HOSP	St. Francis Hospital - Bartlett	2013	2	Fixed	0	3518	$10,412,170.00
Shelby	HOSP	St. Jude Children's Research Hospital	2011	3	Fixed	0	10031	$34,100,476.00
Shelby	HOSP	St. Jude Children's Research Hospital	2012	4	Fixed	0	8737	$33,781,143.00
Shelby	HOSP	St. Jude Children's Research Hospital	2013	4	Fixed	0	8305	$32,149,154.00
Shelby	PO	Wesley Neurology Clinic, P.C.	2011	1	Fixed (Shared)	0	1398	$1,303,736.00
Shelby	PO	Wesley Neurology Clinic, P.C.	2012	1	Fixed (Shared)	0	1309	$1,190,839.00
Shelby	PO	Wesley Neurology Clinic, P.C.	2013	1	Fixed (Shared)	0	1026	$1,109,109.00
Shelby	ASTC/ODC	West Clinic, P.C., The	2011	1	Fixed	0	1662	$2,844,154.00
Shelby	ASTC/ODC	West Clinic, P.C., The	2012	1	Fixed	0	1564	$5,918,456.00
Shelby	ASTC/ODC	West Clinic, P.C., The	2013	1	Fixed	0	1287	$5,283,915.00
Smith	HOSP	Riverview Regional Medical Center	2011	1	Fixed	0	701	$1,939,289.00
Smith	HOSP	Riverview Regional Medical Center	2012	1	Fixed	0	619	$1,954,271.00
Smith	HOSP	Riverview Regional Medical Center	2013	1	Fixed	0	613	$2,139,517.00
Sullivan	PO	Appalachian Orthopaedic Associates, PC	2011	1	Fixed	0	288	$306,612.00
Sullivan	PO	Appalachian Orthopaedic Associates, PC	2012	1	Fixed	0	268	$285,251.00
Sullivan	PO	Appalachian Orthopaedic Associates, PC	2013	1	Fixed	0	214	$227,674.00
Sullivan	HOSP	Bristol Regional Medical Center	2011	2	Fixed	0	6447	$15,040,686.00
Sullivan	HOSP	Bristol Regional Medical Center	2012	2	Fixed	0	6578	$16,514,769.00
Sullivan	HOSP	Bristol Regional Medical Center	2013	2	Fixed	0	6323	$17,397,570.00
Sullivan	ODC	Holston Valley Imaging Center, LLC	2011	3	Fixed	0	8362	$21,350,027.00
Sullivan	ODC	Holston Valley Imaging Center, LLC	2012	3	Fixed	0	8792	$23,247,137.00
Sullivan	ODC	Holston Valley Imaging Center, LLC	2013	3	Fixed	0	8787	$23,567,834.00

Health Care Providers that Utilize MRI's - Utilization *(As of 8/11/2014)*

County	Provider Type	Provider	Year	Number of	Mobile?	MobileDays	Total Procedures	Total Gross Charges
Sullivan	HOSP	Holston Valley Medical Center	2011	1	Fixed	0	3774	$8,021,398.00
Sullivan	HOSP	Holston Valley Medical Center	2012	1	Fixed	0	3514	$8,267,524.00
Sullivan	HOSP	Holston Valley Medical Center	2013	1	Fixed	0	3326	$8,994,777.00
Sullivan	HOSP	Indian Path Medical Center	2011	1	Fixed	0	2651	$10,206,168.00
Sullivan	HOSP	Indian Path Medical Center	2012	1	Fixed	0	3000	$12,399,451.00
Sullivan	HOSP	Indian Path Medical Center	2013	1	Fixed	0	2807	$12,275,782.00
Sullivan	ODC	Meadowview Outpatient Diagnostic Center	2011	1	Fixed	0	4457	$7,583,560.00
Sullivan	ODC	Meadowview Outpatient Diagnostic Center	2012	1	Fixed	0	4484	$3,923,500.00
Sullivan	ODC	Meadowview Outpatient Diagnostic Center	2013	1	Fixed	0	4350	$7,378,329.00
Sullivan	ODC	Sapling Grove Outpatient Diagnostic Center	2011	1	Fixed	0	2587	$4,325,318.00
Sullivan	ODC	Sapling Grove Outpatient Diagnostic Center	2012	1	Fixed	0	2309	$1,888,694.00
Sullivan	ODC	Sapling Grove Outpatient Diagnostic Center	2013	1	Fixed	0	2245	$3,900,816.00
Sullivan	HODC	Volunteer Parkway Imaging Center	2011	1	Fixed	0	1327	$3,139,473.00
Sullivan	HODC	Volunteer Parkway Imaging Center	2012	1	Fixed	0	1348	$3,333,200.00
Sullivan	HODC	Volunteer Parkway Imaging Center	2013	1	Fixed	0	1239	$3,297,136.00
Sumner	H-Imaging	Diagnostic Center at Sumner Station	2011	1	Fixed	0	1413	$4,021,765.00
Sumner	H-Imaging	Diagnostic Center at Sumner Station	2012	1	Fixed	0	1707	$5,537,511.00
Sumner	H-Imaging	Diagnostic Center at Sumner Station	2013	1	Fixed	0	1948	$6,851,447.00
Sumner	HODC	Outpatient Imaging Center at Hendersonville Medical Center	2011	1	Fixed	0	2163	$7,639,253.00
Sumner	HODC	Outpatient Imaging Center at Hendersonville Medical Center	2012	1	Fixed	0	2116	$8,153,088.00
Sumner	HODC	Outpatient Imaging Center at Hendersonville Medical Center	2013	1	Fixed	0	1670	$8,192,037.00
Sumner	H-Imaging	Portland Diagnostic Center	2011	1	Mobile (Part)	1 day/week	224	$770,888.00
Sumner	H-Imaging	Portland Diagnostic Center	2012	1	Mobile (Part)	1 day/week	247	$878,818.00
Sumner	H-Imaging	Portland Diagnostic Center	2013	1	Mobile (Part)	1 day/week	289	$1,325,227.00
Sumner	PO	Southern Sports Medicine Institute, PLLC	2011	1	Fixed	0	636	$815,384.00
Sumner	PO	Southern Sports Medicine Institute, PLLC	2012	1	Fixed	0	720	$935,674.00
Sumner	PO	Southern Sports Medicine Institute, PLLC	2013	1	Fixed	0	723	$1,135,395.00
Sumner	HOSP	Sumner Regional Medical Center	2011	1	Fixed	0	2578	$7,829,720.00
Sumner	HOSP	Sumner Regional Medical Center	2012	1	Fixed	0	2591	$8,957,666.00
Sumner	HOSP	Sumner Regional Medical Center	2013	1	Fixed	0	3064	$11,707,305.00
Sumner	HOSP	TriStar Hendersonville Medical Center	2011	1	Fixed	0	2367	$8,745,833.00
Sumner	HOSP	TriStar Hendersonville Medical Center	2012	1	Fixed	0	2367	$9,667,539.00
Sumner	HOSP	TriStar Hendersonville Medical Center	2013	1	Fixed	0	2565	$13,749,704.00
Tipton	HOSP	Baptist Memorial Hospital - Tipton	2011	1	Fixed	0	1143	$2,374,682.00
Tipton	HOSP	Baptist Memorial Hospital - Tipton	2012	1	Fixed	0	1265	$2,968,721.00
Tipton	HOSP	Baptist Memorial Hospital - Tipton	2013	1	Fixed	0	1153	$3,041,798.00

Health Care Providers that Utilize MRI's - Utilization *(As of 8/11/2014)*

County	Provider Type	Provider	Year	Number of	Mobile?	MobileDays	Total Procedures	Total Gross Charges
Unicoi	HOSP	Unicoi County Memorial Hospital, Inc.	2011	1	Fixed	0	1630	$4,444,850.00
Unicoi	HOSP	Unicoi County Memorial Hospital, Inc.	2012	1	Fixed	0	1164	$1,889,762.00
Unicoi	HOSP	Unicoi County Memorial Hospital, Inc.	2013	1	Fixed	0	935	$2,150,470.00
Warren	HOSP	River Park Hospital	2011	1	Fixed	0	2653	$7,941,439.50
Warren	HOSP	River Park Hospital	2012	1	Fixed	0	2390	$7,277,951.00
Warren	HOSP	River Park Hospital	2013	1	Fixed	0	2323	$7,387,079.29
Washington	PO	Appalachian Orthopaedic Associates - Johnson City	2011	1	Fixed	0	546	$580,870.00
Washington	PO	Appalachian Orthopaedic Associates - Johnson City	2012	1	Fixed	0	357	$379,095.00
Washington	PO	Appalachian Orthopaedic Associates - Johnson City	2013	1	Fixed	0	188	$199,865.00
Washington	HOSP	Franklin Woods Community Hospital	2011	1	Fixed	0	3546	$13,513,297.00
Washington	HOSP	Franklin Woods Community Hospital	2012	1	Fixed	0	3499	$14,456,022.00
Washington	HOSP	Franklin Woods Community Hospital	2013	1	Fixed	0	3529	$15,556,198.00
Washington	HOSP	Johnson City Medical Center	2011	2	Fixed	0	7247	$27,926,965.00
Washington	HOSP	Johnson City Medical Center	2012	2	Fixed	0	7237	$30,285,871.00
Washington	HOSP	Johnson City Medical Center	2013	2	Fixed	0	6617	$29,626,271.00
Washington	ODC	Mountain States Imaging at Med Tech Parkway	2011	1	Fixed	0	2738	$10,180,477.00
Washington	ODC	Mountain States Imaging at Med Tech Parkway	2012	1	Fixed	0	2697	$10,964,043.00
Washington	ODC	Mountain States Imaging at Med Tech Parkway	2013	1	Fixed	0	2448	$10,545,194.00
Washington	PO	Watauga Orthopaedics, PLC	2011	1	Fixed	0	2748	$3,875,113.16
Washington	PO	Watauga Orthopaedics, PLC	2012	1	Fixed	0	2415	$3,488,641.00
Washington	PO	Watauga Orthopaedics, PLC	2013	1	Fixed	0	2337	$3,389,074.00
Wayne	HOSP	Wayne Medical Center	2011	1	Mobile (Part)	2 days/week	444	$1,058,449.00
Wayne	HOSP	Wayne Medical Center	2012	1	Mobile (Part)	2 days/week	555	$1,328,376.00
Wayne	HOSP	Wayne Medical Center	2013	1	Mobile (Part)	2 days/week	581	$1,408,034.00
Weakley	HOSP	Volunteer Community Hospital	2011	1	Fixed	0	1216	$3,511,278.00
Weakley	HOSP	Volunteer Community Hospital	2012	1	Fixed	0	1233	$3,913,088.60
Weakley	HOSP	Volunteer Community Hospital	2013	1	Fixed	0	1037	$3,525,445.00
White	HOSP	Highlands Medical Center	2011	1	Fixed	0	994	$1,533,183.00
White	HOSP	Highlands Medical Center	2012	1	Fixed	0	1069	$1,953,155.00
White	HOSP	Highlands Medical Center	2013	1	Fixed	0	961	$1,852,766.00
Williamson	ODC	Cool Springs Imaging	2011	1	Fixed	0	4373	$6,800,124.00
Williamson	ODC	Cool Springs Imaging	2012	1	Fixed	0	4308	$7,236,220.00
Williamson	ODC	Cool Springs Imaging	2013	1	Fixed	0	4552	$7,626,899.00
Williamson	ODC	Premier Radiology Cool Springs	2011	1	Fixed	0	3914	$6,586,341.00
Williamson	ODC	Premier Radiology Cool Springs	2012	1	Fixed	0	3683	$7,533,817.00
Williamson	ODC	Premier Radiology Cool Springs	2013	2	Fixed	0	3151	$6,116,985.00

Health Care Providers that Utilize MRI's - Trend

Medical Equipment Registry - 8/14/2014

County	Provider Type	Provider	Procedures 2011		2012		2013		Percent Changed
Anderson	HOSP	Methodist Medical Center - Oak Ridge	(2)	6417	(2)	6467	(2)	6896	7.46%
Anderson	PO	OrthoTennessee Imaging Oak Ridge	(1)	594	(1)	581	(1)	514	-13.47%
Anderson	PO	Tennessee Orthopaedic Clinics - Oak Ridge	(1)	993	(1)	1078	(1)	1066	7.35%
Bedford	HOSP	Heritage Medical Center	(2)	1401	(1)	1439	(1)	1131	-19.27%
Bedford	H-Imaging	Heritage Medical Center/Advanced Orthopedics (Stopped 2012)	(1)	0	(1)	1	(1)	0	0.00%
Benton	HOSP	Camden General Hospital	(1-1/week)	302	(1-1/week)	352	(1-1/week)	345	14.24%
Blount	HOSP	Blount Memorial Hospital	(1)	5551	(1)	5257	(1)	6909	24.46%
Blount	HODC	Blount Memorial Springbrook Diagnostic Center	(1)	2370	(1)	2493	(1)	707	-70.17%
Blount	PO	OrthoTennessee Imaging/Maryville Orthopaedic	(1)	932	(1)	855	(1)	741	-20.49%
Bradley	PO	Cleveland Imaging	(1)	668	(1)	2769	(1)	3509	425.30%
Bradley	HOSP	Skyridge Medical Center	(1)	2584	(1)	2499	(1)	2302	-10.91%
Bradley	HOSP	Skyridge Medical Center - Westside	(2)	3214	(2)	2493	(2)	1818	-43.43%
Campbell	HOSP	Jellico Community Hospital	(1)	686	(1)	317	(1)	288	-58.02%
Campbell	HOSP	Lafollette Medical Center	(1-5/week)	939	(1-5/week)	1285	(1-5/week)	1225	30.46%
Cannon	HOSP	Stones River Hospital	(1)	576	(1)	451	(1)	379	-34.20%
Carroll	HOSP	Baptist Memorial Hospital - Huntingdon	(1)	1119	(1)	986	(1)	909	-18.77%
Carroll	ODC	McKenzie Medical Center	(1)	1840	(1)	2279	(1)	1681	-8.64%
Carroll	HOSP	McKenzie Regional Hospital	(1-1/week)	87	(1-1/week)	79	(1-1/week)	25	-71.26%
Carter	HOSP	Sycamore Shoals Hospital	(1)	1958	(1)	2014	(1)	1719	-12.21%
Cheatham	HOSP	TriStar Ashland City Medical Center	(1-2/week)	322	(1-2/week)	375	(1-2/week)	303	-5.90%
Chester	PO	Frix Jennings Clinic, PC	(1-4 half/week)	667	(1-4 half/week)	637	(1-4 half/week)	715	7.20%
Claiborne	HOSP	Claiborne County Hospital	(1)	8168	(1)	1642	(1)	1436	-82.42%
Cocke	HOSP	Newport Medical Center	(1)	1519	(1)	1255	(1)	1274	-16.13%
Coffee	HOSP	Harton Regional Medical Center (John W.)	(1)	2983	(1)	2746	(1)	2538	-14.92%
Coffee	HOSP	Medical Center of Manchester	(1-2/week)	671	(1)	705	(1)	632	-5.81%
Coffee	HOSP	United Regional Medical Center	(1)	2020	(1)	2107	(1)	1615	-20.05%
Cumberland	HOSP	Cumberland Medical Center, Inc.	(2)	4266	(2)	4979	(2)	4708	10.36%
Davidson	ODC	Belle Meade Imaging	(1)	2511	(1)	2817	(1)	3085	22.86%
Davidson	PO	Center for Inflammatory Disease	(1)	130	(1)	63	(1)	19	-85.38%
Davidson	PO	Elite Sports Medicine & Orthopaedic Center	(2)	4793	(2)	4781	(2)	4771	-0.46%
Davidson	PO	Heritage Medical Associates - Murphy Avenue	(1-Shared)	639	(1-Shared)	1831	(1-Shared)	1965	207.51%
Davidson	ODC	Hillsboro Imaging	(1)	2869	(1)	3968	(1)	4252	48.20%
Davidson	ODC	Millennium MRI, LLC	(1-Shared)	371	(1-Shared)	366	(1-Shared)	451	21.56%
Davidson	PO	Nashville Bone and Joint	(1-Shared)	947	(1-Shared)	953	(1-Shared)	939	-0.84%
Davidson	HOSP	Nashville General Hospital	(1)	1842	(1)	1481	(1)	1775	-3.64%
Davidson	PO	Neurological Surgeons, PC Imaging Office	(1)	6052	(1)	4305	(1)	4891	-19.18%
Davidson	ODC	Next Generation Imaging, LLC	(1-Shared)	740	(1-Shared)	649	(1-Shared)	859	16.08%
Davidson	H-Imaging	One Hundred Oaks Breast Center	(1)	586	(1)	679	(1)	682	16.38%
Davidson	ODC	One Hundred Oaks Imaging	(1)	4433	(2)	5226	(2)	5430	22.49%
Davidson	ODC	Outpatient Diagnostic Center of Nashville	(2)	3865	(2)	4878	(2)	5044	30.50%
Davidson	PO	Pain Management Group, PC	(1)	1715	(1)	2451	(1)	2712	58.13%
Davidson	ODC	Premier Orthopeadics and Sports Medicine	(2)	6229	(2)	5214	(2)	4471	-28.22%
Davidson	ODC	Premier Radiology Belle Meade	(3)	7872	(3)	7686	(3)	6929	-11.98%
Davidson	ODC	Premier Radiology Brentwood	(1-5/week)	931	(1-5/week)	1058	(1)	1356	45.65%

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County	Provider Type	Provider	Procedures 2011		Procedures 2012		Procedures 2013		Percent Changed
Davidson	ODC	Premier Radiology Hermitage	(2)	4931	(2)	4943	(2)	4603	-6.65%
Davidson	ODC	Premier Radiology Midtown	(0)	0	(0)	0	(2)	1351	0.00%
Davidson	ODC	Premier Radiology Nashville	(1)	2492	(1)	2376	(1)	2072	-16.85%
Davidson	ODC	Specialty MRI	(1-Shared)	1562	(1-Shared)	1467	(1-Shared)	1158	-25.86%
Davidson	ODC	St. Thomas Heart (Stopped 2013)	(1)	2076	(1)	1609	(0)	0	-100.00%
Davidson	HOSP	St. Thomas Midtown Hospital (fka Baptist Hospital)	(3)	5920	(3)	4752	(2)	3249	-45.12%
Davidson	HOSP	St. Thomas West Hospital (fka St. Thomas Hospital)	(3)	5643	(4)	5631	(2)	5464	-3.17%
Davidson	PO	Tennessee Oncology, PET Services	(0)	0	(1)	279	(1)	1168	0.00%
Davidson	PO	Tennessee Orthopaedic Alliance Imaging	(3)	7181	(3)	7163	(3)	6325	-11.92%
Davidson	HOSP	TriStar Centennial Medical Center	(3)	7561	(3)	7996	(3)	8840	16.92%
Davidson	HOSP	TriStar Skyline Medical Center	(2)	7339	(2)	7930	(2)	8234	12.20%
Davidson	HOSP	TriStar Southern Hills Medical Center	(1)	2528	(1)	2659	(1)	2740	8.39%
Davidson	HOSP	TriStar Summit Medical Center	(1)	3723	(1)	4008	(1)	4020	7.98%
Davidson	HODC	TriStar Summit Medical Center - ODC	(1-Shared)	1858	(1-Shared)	1918	(1-Shared)	2249	21.04%
Davidson	HOSP	Vanderbilt University Hospital	(6)	27040	(6)	28706	(6)	29507	9.12%
Decatur	HOSP	Decatur County General Hospital	(1-1/week)	405	(1-1/week)	360	(1-1/week)	451	11.36%
DeKalb	HOSP	DeKalb Community Hospital	(1)	875	(1)	901	(1)	784	-10.40%
Dickson	PO	Dickson Medical Associates South	(1)	1942	(1)	1658	(1)	1994	2.68%
Dickson	HODC	Natchez Imaging Center	(1)	368	(1)	427	(1)	484	31.52%
Dickson	HOSP	TriStar Horizon Medical Center	(1)	1045	(1)	1287	(1)	1590	52.15%
Dyer	HOSP	Dyersburg Regional Medical Center	(1)	2279	(1)	2230	(1)	1852	-18.74%
Fayette	HOSP	Methodist Healthcare-Fayette Hospital	(1-1/week)	324	(1-1/week)	271	(1-1/week)	204	-37.04%
Fentress	ODC	Fentress Health Systems	(1)	1793	(1)	2191	(1)	1991	11.04%
Franklin	HOSP	Southern Tennessee Regional Health System - Winchester (fka Southern Tennessee Medical Center)	(1)	2341	(1)	2658	(1)	2220	-5.17%
Franklin	ODC	Summit Open MRI, Inc.	(1)	635	(1)	723	(1)	623	-1.89%
Giles	HOSP	Southern Tennessee Regional Health System - Pulaski (fka Hillside Hospital)	(1)	901	(1)	581	(1)	810	-10.10%
Greene	HOSP	Laughlin Memorial Hospital, Inc.	(2)	3648	(2)	3379	(2)	3159	-13.40%
Greene	HOSP	Takoma Regional Hospital	(1)	1419	(1)	1635	(1)	1610	13.46%
Hamblen	PO	Healthstar Physicians, PC	(2)	3911	(2)	2793	(2)	3217	-17.74%
Hamblen	HOSP	Lakeway Regional Hospital	(1)	2105	(1)	2288	(1)	2625	24.70%
Hamblen	HOSP	Morristown-Hamblen Hospital	(2)	3677	(2)	4560	(2)	4211	14.52%
Hamilton	PO	Chattanooga Bone & Joint Surgeons, PC	(1)	1119	(1)	1021	(1)	841	-24.84%
Hamilton	ODC	Chattanooga Imaging Downtown	(2)	2044	(2)	2035	(2)	1540	-24.66%
Hamilton	RPO	Chattanooga Imaging East	(2)	4552	(1)	2850	(1)	2822	-38.01%
Hamilton	RPO	Chattanooga Imaging Hixson	(1)	2117	(1)	2230	(1)	2386	12.71%
Hamilton	PO	Chattanooga Orthopaedic Group PC	(1)	5698	(1)	5332	(1)	5340	-6.28%
Hamilton	ODC	Chattanooga Outpatient Center (Digital Imaging of North Georgia)	(1)	6045	(1)	6465	(2)	7292	20.63%
Hamilton	H-Imaging	Erlanger East Campus	(1)	1275	(1)	704	(1)	568	-55.45%
Hamilton	HOSP	Erlanger Medical Center	(3)	10730	(3)	10915	(3)	11558	7.72%
Hamilton	HOSP	Memorial Hixson Hospital	(2)	4048	(2)	2836	(2)	2488	-38.54%
Hamilton	HOSP	Memorial Hospital	(3)	8211	(3)	4096	(3)	4356	-46.95%

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County	Provider Type	Provider	Procedures 2011		2012		2013		Percent Changed
Hamilton	H-Imaging	Memorial Ooltewah Imaging Center	(1)	1286	(1)	1050	(1)	1049	-18.43%
Hamilton	PO	Neurosurgical Group of Chattanooga, P.C.	(1)	1388	(1)	1405	(1)	1198	-13.69%
Hamilton	HOSP	Parkridge East Hospital	(1)	934	(1)	919	(1)	1024	9.64%
Hamilton	HOSP	Parkridge Medical Center	(1)	2320	(1)	2496	(1)	2054	-11.47%
Hamilton	RPO	Tennessee Imaging and Vein Center	(1)	2615	(1)	3074	(1)	3165	21.03%
Hardin	HOSP	Hardin Medical Center	(1)	1449	(1)	1379	(1)	1470	1.45%
Hawkins	HOSP	Hawkins County Memorial Hospital	(1-3/week)	1065	(1-3/week)	895	(1-3/week)	877	-17.65%
Haywood	HOSP	Haywood Park Community Hospital	(1-1/week)	222	(1-1/week)	206	(1-1/week)	179	-19.37%
Henderson	HOSP	Henderson County Community Hospital	(1-3/week)	474	(1-3/week)	504	(1-3/week)	411	-13.29%
Henry	HOSP	Henry County Medical Center	(2)	2691	(2)	2918	(2)	3257	21.03%
Hickman	HOSP	St. Thomas Hickman Hospital (fka Hickman Community Hospital)	(1-1/week)	147	(1-1/week)	214	(1-1/week)	247	68.03%
Houston	HOSP	Houston County Community Hospital	(1-1/week)	191	(1-1/week)	223	(1-1/week)	74	-61.26%
Jefferson	HOSP	Jefferson Memorial Hospital	(1-6/week)	2714	(1-6/week)	3098	(1-7/week)	2074	-23.58%
Johnson	HOSP	Johnson County Community Hospital	(1-2/month)	274	(1-4/month)	308	(1-4/month)	267	-2.55%
Knox	RPO	Abercrombie Radiological Consultants, Inc.	(2)	4856	(2)	4732	(2)	4313	-11.18%
Knox	PO	Ancillary Services, Summit Medical Group	(1)	3320	(1)	3021	(1)	2768	-16.63%
Knox	PO	Ancillary Svcs-Summit Medical Group-Midlake	(1)	2318	(1)	2273	(1)	2317	-0.04%
Knox	HOSP	East Tennessee Children's Hospital	(1)	2524	(1)	2594	(1)	2674	5.94%
Knox	ODC	East Tennessee Community Open MRI, LLC	(2)	1783	(2)	1860	(2)	1845	3.48%
Knox	HOSP	Fort Sanders Regional Medical Center	(2)	7127	(2)	7269	(2)	7461	4.69%
Knox	HODC	Fort Sanders West Diagnostic Center	(1)	1588	(1)	1346	(1)	1099	-30.79%
Knox	PO	Knoxville Comprehensive Breast Center	(2)	2200	(2)	1014	(2)	1809	-17.77%
Knox	HOSP	North Knoxville Medical Center	(1)	5191	(1)	3984	(1)	3696	-28.80%
Knox	PO	OrthoTennessee Imaging Fort Sanders West	(1)	3761	(1)	4999	(1)	3971	5.58%
Knox	ODC	Outpatient Diagnostic Ctr of Knoxville	(2)	7680	(2)	8040	(2)	8186	6.59%
Knox	HOSP	Parkwest Medical Center	(2)	9615	(2)	8254	(2)	8038	-16.40%
Knox	HOSP	Physicians Regional Medical Center	(2)	6163	(2)	4779	(2)	5421	-12.04%
Knox	PO	Tennessee Orthopaedic Clinics - Regional MRI	(1)	952	(1)	1011	(1)	995	4.52%
Knox	PO	Tennessee Orthopaedic Clinics, PC	(1)	3272	(1)	3425	(1)	3259	-0.40%
Knox	HOSP	Turkey Creek Medical Center	(1)	2875	(1)	3342	(1)	2507	-12.80%
Knox	HOSP	University of Tennessee Medical Hospital	(4)	17037	(4)	17557	(4)	16453	-3.43%
Lauderdale	HOSP	Lauderdale Community Hospital	(1-4/week)	447	(1-4/week)	389	(1-4/week)	292	-34.68%
Lawrence	HOSP	Southern Tennessee Regional Health System - Lawrenceburg (fka Crockett Hospital)	(1)	1373	(1)	1622	(1)	1441	4.95%
Lewis	H-Imaging	Lewis Health Center	(1-1/week)	397	(1-1/week)	477	(1-1/week)	500	25.94%
Lincoln	HOSP	Lincoln Medical Center	(1)	1213	(1)	1284	(1)	1182	-2.56%
Loudon	HOSP	Fort Loudoun Medical Center	(1)	2246	(1)	2300	(1)	2023	-9.93%
Macon	HOSP	Macon County General Hospital	(1-3/week)	445	(1-2/week)	793	(1-2/week)	480	7.87%
Madison	PO	Jackson Clinic, P.A., The	(1)	1416	(1)	2271	(1)	2019	42.58%
Madison	HOSP	Jackson Madison County General Hospital	(2)	9657	(2)	9877	(2)	9372	-2.95%
Madison	HOSP	Regional Hospital of Jackson	(1)	1805	(1)	2203	(1)	2123	17.62%
Madison	ODC	Sports Orthopedics and Spine	(1)	4688	(1)	6781	(1)	8835	88.46%
Madison	PO	West Tennessee Bone & Joint Clinic	(1)	3248	(1)	2649	(1)	2804	-13.67%
Madison	HODC	West Tennessee Imaging Center	(3)	6624	(3)	7027	(3)	6491	-2.01%

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County	Provider Type	Provider	Procedures 2011		2012		2013		Percent Changed
Madison	PO	West Tennessee Neurosciences	(1)	2772	(1)	2706	(1)	2729	-1.55%
Marion	HOSP	Parkridge West Hospital (fka Grandview Medical Center)	(1)	884	(1)	953	(1)	884	0.00%
Marshall	HOSP	Marshall Medical Center	(1)	604	(1)	700	(1)	773	27.98%
Maury	HOSP	Maury Regional Medical Center	(3)	5724	(3)	6083	(3)	6109	6.73%
Maury	PO	Mid Tennessee Bone and Joint Clinic, PC	(1)	2188	(1)	1909	(1)	2047	-6.44%
Maury	RPO	Mobile MRI Services, LLC - Columbia	(0)	0	(1-2/week)	415	(1-0/week)	0	0.00%
Maury	ODC	Spring Hill Imaging Center (Maury Regional Imaging Ctr)	(1)	1726	(1)	1897	(1)	2392	38.59%
McMinn	HOSP	Starr Regional Medical Center - Etowah (fka Woods Memorial Hospital)	(1)	1028	(1)	1078	(1)	479	-53.40%
McMinn	HOSP	Starr Regional Medical Center (fka Athens Regional Medical Center)	(1)	2112	(1)	2295	(1)	2437	15.39%
McNairy	HOSP	McNairy Regional Hospital	(1-2/week)	554	(1-2/week)	642	(1-2/week)	545	-1.62%
Monroe	HOSP	Sweetwater Hospital Association	(1)	1681	(1-5/week)	1638	(1-5/week)	1834	9.10%
Montgomery	ODC	Clarksville Imaging Center, LLC	(1)	3803	(1)	4119	(1)	4276	12.44%
Montgomery	HOSP	Gateway Medical Center	(2)	5426	(2)	5242	(2)	4432	-18.32%
Montgomery	RPO	Mobile MRI Services, LLC - Clarksville	(1-3/week)	0	(1-3/week)	1129	(1-5/week)	1404	0.00%
Montgomery	PO	Premier Medical Group, P.C.	(1)	1494	(1)	1426	(1)	1386	-7.23%
Montgomery	PO	Tennessee Orthopaedic Alliance	(1)	2007	(1)	1915	(1)	1932	-3.74%
Obion	HOSP	Baptist Memorial Hospital - Union City	(1)	2111	(1)	2066	(1)	1784	-15.49%
Overton	HOSP	Livingston Regional Hospital	(1)	1064	(1)	959	(1)	949	-10.81%
Polk	HOSP	Copper Basin Medical Center	(1-1/week)	239	(1-1/week)	176	(1-1/week)	250	4.60%
Putnam	HOSP	Cookeville Regional Medical Center	(2)	8001	(1)	4928	(1)	3701	-53.74%
Putnam	H-Imaging	Outpatient Imaging Center at Cookeville Regional Med. Ctr.	(1)	0	(2)	3385	(2)	4791	0.00%
Putnam	ODC	Premier Diagnostic Imaging, LLC	(2)	5707	(2)	5572	(2)	5674	-0.58%
Rhea	HOSP	Rhea Medical Center	(1)	1289	(1)	1530	(1)	1481	14.90%
Roane	HOSP	Roane Medical Center	(1)	1958	(1)	1914	(1)	1729	-11.70%
Robertson	HOSP	Northcrest Medical Center	(1)	2606	(1)	2780	(1)	3232	24.02%
Rutherford	ODC	Imaging Center of Murfreesboro	(1)	4307	(1)	2000	(1)	4827	12.07%
Rutherford	PO	Murfreesboro Medical Clinic-Garrison Drive	(1)	1963	(1)	2189	(1)	1994	1.58%
Rutherford	ODC	Premier Radiology Murfreesboro (fka Middle Tennessee Imaging Murfreesboro)	(1)	3006	(2)	4800	(2)	5169	71.96%
Rutherford	ODC	Premier Radiology Smyrna (fka Middle Tennessee Imaging Smyrna)	(1)	1601	(1)	2502	(1)	2392	49.41%
Rutherford	RPO	Radiology & Diagnostics, PLC (Closed 2013)	(1)	932	(1)	919	(0)	0	-100.00%
Rutherford	HOSP	St. Thomas Rutherford Hospital (fka Middle Tennessee Medical Center)	(2)	2544	(2)	2345	(2)	1964	-22.80%
Rutherford	PO	Tennessee Orthopaedic Alliance Imaging	(1)	3901	(1)	4120	(1)	4148	6.33%
Rutherford	HOSP	TriStar Stonecrest Medical Center	(1)	1877	(1)	2162	(1)	2369	26.21%
Scott	H-Imaging	Scott County Hosp. MRI (Stopped service in 2012)	(1)	793	(1)	0	(0)	0	-100.00%
Sevier	HOSP	LeConte Medical Center	(1)	4264	(1)	4269	(1)	4235	-0.68%
Shelby	HOSP	Baptist Memorial Hospital - Collierville	(1)	1891	(1)	1734	(1)	1593	-15.76%
Shelby	HOSP	Baptist Memorial Hospital - Memphis	(3)	12052	(3)	11913	(3)	11280	-6.41%
Shelby	HOSP	Baptist Memorial Hospital for Women	(0)	0	(0)	0	(1)	72	#DIV/0!

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County	Provider Type	Provider	Procedures 2011		2012		2013		Percent Changed
Shelby	HOSP	Baptist Rehabilitation - Germantown	(1)	1622	(1)	1596	(1)	1212	-25.28%
Shelby	H-Imaging	Baptist Rehabilitation Germantown - Briarcrest MRI	(1-Shared)	585	(1-Shared)	650	(1-Shared)	613	4.79%
Shelby	PO	Campbell Clinic - Union	(1)	2290	(1)	2155	(1)	2539	10.87%
Shelby	PO	Campbell Clinic Inc	(1)	6502	(1)	6321	(1)	5547	-14.69%
Shelby	HOSP	Delta Medical Center	(1)	1006	(1)	787	(1)	674	-33.00%
Shelby	RPO	Diagnostic Imaging PC - Memphis	(1)	6358	(1)	6538	(1)	6737	5.96%
Shelby	HOSP	LeBonheur Children's Medical Center	(3)	4663	(3)	5357	(3)	5333	14.37%
Shelby	HOSP	Methodist Healthcare-Germantown Hospital	(2)	7698	(2)	6557	(2)	6892	-10.47%
Shelby	HOSP	Methodist Healthcare-North Hospital	(2)	6058	(2)	6092	(2)	6003	-0.91%
Shelby	HOSP	Methodist Healthcare-South Hospital	(1)	4073	(1)	4139	(1)	4090	0.42%
Shelby	HOSP	Methodist Healthcare-University Hospital	(3)	9677	(3)	9803	(3)	10524	8.75%
Shelby	PO	MSK Group PC - New Covington Pike	(1)	3096	(1)	3140	(1)	3013	-2.68%
Shelby	PO	MSK Group, PC - Briarcrest	(1-Shared)	4508	(1-Shared)	4489	(1-Shared)	4637	2.86%
Shelby	PO	Neurology Clinic, PC	(1-Shared)	3168	(1-Shared)	3160	(1-Shared)	3312	4.55%
Shelby	ODC	Outpatient Diagnostic Ctr of Memphis	(1)	2207	(1)	2214	(1)	2563	16.13%
Shelby	ODC	Park Avenue Diagnostic Center	(2)	3080	(2)	2681	(2)	2075	-32.63%
Shelby	HOSP	Regional Medical Center at Memphis (The Med)	(1)	3927	(1)	4491	(1)	4131	5.19%
Shelby	PO	Semmes-Murphey Clinic (Humphreys Blvd)	(2)	7300	(2)	6490	(2)	6277	-14.01%
Shelby	HOSP	St. Francis Hospital	(3)	5482	(3)	5393	(3)	5326	-2.85%
Shelby	HOSP	St. Francis Hospital - Bartlett	(2)	3257	(2)	3642	(2)	3518	8.01%
Shelby	HOSP	St. Jude Children's Research Hospital	(3)	10031	(4)	8737	(4)	8305	-17.21%
Shelby	PO	Wesley Neurology Clinic, P.C.	(1-Shared)	1398	(1-Shared)	1309	(1-Shared)	1026	-26.61%
Shelby	ASTC/ODC	West Clinic, P.C., The	(1)	1662	(1)	1564	(1)	1287	-22.56%
Smith	HOSP	Riverview Regional Medical Center	(1)	701	(1)	619	(1)	613	-12.55%
Sullivan	PO	Appalachian Ortho. Associates - Kingsport (Unit sold in 2012)	(1)	1460	(0)	0	(0)	0	-100.00%
Sullivan	PO	Appalachian Orthopaedic Associates, PC	(1)	288	(1)	268	(1)	214	-25.69%
Sullivan	HOSP	Bristol Regional Medical Center	(2)	6447	(2)	6578	(2)	6323	-1.92%
Sullivan	ODC	Holston Valley Imaging Center, LLC	(3)	8362	(3)	8792	(3)	8787	5.08%
Sullivan	HOSP	Holston Valley Medical Center	(1)	3774	(1)	3514	(1)	3326	-11.87%
Sullivan	HOSP	Indian Path Medical Center	(1)	2651	(1)	3000	(1)	2807	5.88%
Sullivan	ODC	Meadowview Outpatient Diagnostic Center	(1)	4457	(1)	4484	(1)	4350	-2.40%
Sullivan	H-Imaging	Sapling Grove Imaging, LLC (Wellmont) (Sold 2012)	(1)	349	(1)	150	(0)	0	-100.00%
Sullivan	ODC	Sapling Grove Outpatient Diagnostic Center	(1)	2587	(1)	2309	(1)	2245	-13.22%
Sullivan	HODC	Volunteer Parkway Imaging Center	(1)	1327	(1)	1348	(1)	1239	-6.63%
Sumner	H-Imaging	Diagnostic Center at Sumner Station	(1)	1413	(1)	1707	(1)	1948	37.86%
Sumner	HODC	Outpatient Imaging Center at Hendersonville Medical Center	(1)	2163	(1)	2116	(1)	1670	-22.79%
Sumner	H-Imaging	Portland Diagnostic Center	(1-1/week)	224	(1-1/week)	247	(1-1/week)	289	29.02%
Sumner	PO	Southern Sports Medicine Institute, PLLC	(1)	636	(1)	720	(1)	723	13.68%
Sumner	HOSP	Sumner Regional Medical Center	(1)	2578	(1)	2591	(1)	3064	18.85%
Sumner	HOSP	TriStar Hendersonville Medical Center	(1)	2367	(1)	2367	(1)	2565	8.37%
Tipton	HOSP	Baptist Memorial Hospital - Tipton	(1)	1143	(1)	1265	(1)	1153	0.87%
Unicoi	HOSP	Unicoi County Memorial Hospital, Inc.	(1)	1630	(1)	1164	(1)	935	-42.64%
Warren	HOSP	River Park Hospital	(1)	2653	(1)	2390	(1)	2323	-12.44%

Health Care Providers that Utilize MRI's - Trend

Medical Equipment Registry - 8/14/2014

County	Provider Type	Provider	Procedures 2011		2012		2013		Percent Changed
Washington	PO	Appalachian Orthopaedic Associates - Johnson City	(1)	546	(1)	357	(1)	188	-65.57%
Washington	HOSP	Franklin Woods Community Hospital	(1)	3546	(1)	3499	(1)	3529	-0.48%
Washington	HOSP	Johnson City Medical Center	(2)	7247	(2)	7237	(2)	6617	-8.69%
Washington	ODC	Mountain States Imaging at Med Tech Parkway	(1)	2738	(1)	2697	(1)	2448	-10.59%
Washington	PO	Watauga Orthopaedics, PLC	(1)	2748	(1)	2415	(1)	2337	-14.96%
Wayne	HOSP	Wayne Medical Center	(1-2/week)	444	(1-2/week)	555	(1-2/week)	581	30.86%
Weakley	HOSP	Volunteer Community Hospital	(1)	1216	(1)	1233	(1)	1037	-14.72%
White	HOSP	Highlands Medical Center	(1)	994	(1)	1069	(1)	961	-3.32%
Williamson	ODC	Cool Springs Imaging	(1)	4373	(1)	4308	(1)	4552	4.09%
Williamson	ODC	Premier Radiology Cool Springs	(1)	3914	(1)	3683	(1)	3151	-19.49%
Williamson	PO	Vanderbilt Bone and Joint	(1)	2382	(1)	2728	(1)	2743	15.16%
Williamson	HOSP	Williamson Medical Center	(1)	3757	(1)	3654	(1)	4103	9.21%
Wilson	ODC	Premier Radiology - Mt. Juliet	(1-Shared)	2196	(1)	2559	(1)	2562	16.67%
Wilson	PO	Tennessee Orthopedics	(1)	1378	(1)	1197	(1)	1196	-13.21%
Wilson	PO	Tennessee Sports Medicine	(1 & 1-Shared)	1107	(2)	1125	(2)	1801	62.69%
Wilson	HOSP	University Medical Center	(1)	3298	(1)	3000	(1)	2213	-32.90%
		Statewide		**669175**		**660932**		**652252**	**-2.53%**

Attachment C.1.a.MRI Standards and Criteria 7.c.

ACR Guidance Document for Safe MR Practices: 2007

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There are potential risks in the MR environment, not only for the patient [1, 2] but also for the accompanying family members, attending health care professionals, and others who find themselves only occasionally or rarely in the magnetic fields of MR scanners, such as security or housekeeping personnel, firefighters, police, etc. [3–6]. There have been reports in the medical literature and print media detailing magnetic resonance imaging (MRI) adverse incidents involving patients, equipment, and personnel that spotlighted the need for a safety review by an expert panel. To this end, the American College of Radiology (ACR) originally formed the Blue Ribbon Panel on MR Safety. First constituted in 2001, the panel was charged with reviewing existing MR safe practices and guidelines [5–9] and issuing new ones as appropriate for MR examinations. Published initially in 2002 [3], the ACR MR Safe Practice Guidelines established de facto industry standards for safe and responsible practices in clinical and research MR environments. These were subsequently reviewed and updated in May 2004 [4]. After reviewing substantial feedback from the field and installed bases, as well as changes that had transpired throughout the MR industry since the publication of the 2004 version of this document, the panel extensively reviewed, modified, and updated the entire document in 2006–2007.

The present panel consists of the following members: A. James Barkovich, MD; Charlotte Bell, MD (American Society of Anesthesiologists); James P. Borgstede, MD, FACR; William G. Bradley, MD, PhD, FACR; Jerry W. Froelich, MD; Tobias Gilk, architect; J. Rod Gimbel, MD, FACC, cardiologist; John Gosbee, MD, MS; Ellisa Kuhni-Kaminski, RT (R)(MR); Emanuel Kanal, MD, FACR, FISMRM (chair); James W. Lester, MD; John Nyenhuis, PhD; Yoav Parag, MD; Daniel Joe Schaefer, PhD, engineer; Elizabeth A. Sebek-Scoumis, RN, BSN, CRN; Jeffrey Weinreb, MD; Loren A. Zaremba, PhD, FDA; Pamela Wilcox, RN, MBA (ACR staff); Leonard Lucey, JD, LLM (ACR staff); and Nancy Sass, RT (R)(MR)(CT) (ACR staff). The following represents the most recently modified and updated version of the combined prior two re-

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ports [3, 4] issued by the American College of Radiology Blue Ribbon Panel on MR Safety, chaired by Emanuel Kanal, MD, FACR. It is important to note that nothing that appears herein is the result of a "majority vote" of the members of this panel. As with each prior publication of these ACR MR Safe Practice Guidelines, the entire document, from introduction to the markedly expanded appendices, represents the unanimous consensus of each and every member of this Safety Committee and the various areas of expertise that they represent. This includes representation from fields and backgrounds as diverse as MR physicists, research/academic radiologists, private practice radiologists, MR safety experts, patient safety experts/researchers, MR technologists, MR nursing, National Electrical Manufacturers Association, the U.S. Food and Drug Administration (FDA), the American Society of Anesthesiologists, legal counsel, and others. Lay personnel, physicians, PhDs, department chairs and house-staff/residents, government employees and private practitioners, doctors, nurses, technologists, radiologists, anesthesiologists, cardiologists, attorneys—these are all represented on this Committee. It was felt that achieving unanimity for these guidelines was critical in order to demonstrate to all that these guidelines are not only appropriate from a scientific point of view, but are reasonably applicable in the real world in which we all must live, with all its patient care, financial, and throughput pressures and considerations.

The following MR safe practice guidelines document is intended to be used as a template for MR facilities to follow in the development of an MR safety program. These guidelines were developed to help guide MR practitioners regarding these issues and to provide a basis for them to develop and implement their own MR policies and practices. It is intended that these MR safe practice guidelines (and the policies and procedures to which they give rise) be reviewed and updated on a regular basis as the field of MR safety continues to evolve.

The principles behind these MR safe practice guidelines are specifically intended to apply not only to diagnostic settings but also to patient, research subject, and health care personnel safety for all MRI settings, including those designed for clinical diagnostic imaging, research, interventional, and intraoperative MR applications.

With the increasing advent and use of 3.0-Tesla and higher strength magnets, users need to recognize that one should never assume MR compatibility or safety information about a device if it is not clearly documented in writing. Decisions based on published MR safety and compatibility claims should recognize that all such claims apply only to specifically tested conditions, such as static magnetic field strengths, static gradient magnetic field strengths and spatial distributions, and the strengths and rates of change of gradient and radiofrequency (RF) magnetic fields.

Finally, there are many issues that impact MR safety that should be considered during site planning for a given MR installation. These have historically not been dealt with in the prior versions of the ACR MR Safe Practice Guidelines. For the first time, we include in this article, as separate appendices, sections that address such issues as well, including cryogen emergency vent locations and pathways, 5-gauss lines, siting considerations, patient access pathways, etc. Yet despite their appearance herein, these issues, and many others, should be reviewed with those experienced in MR site planning and familiar with the patient safety and patient flow considerations prior to committing to construction of a specific site design. In this regard, enlisting the assistance of an architectural firm experienced in this area, and doing so early in the design stages of the planning process, may prove most valuable.

It remains the intent of the ACR that these MR Safe Practice Guidelines will prove helpful as the field of MRI continues to evolve and mature, providing MR services that are among the most powerful, yet safest, of all diagnostic procedures to be developed in the history of modern medicine.

ACR Guidance Document for Safe MR Practices: 2007

A. Establish, Implement, and Maintain Current MR Safety Policies and Procedures

1. All clinical and research MR sites, irrespective of magnet format or field strength, including installations for diagnostic, research, interventional, and/or surgical applications, should maintain MR safety policies.
2. These policies and procedures should also be reviewed concurrently with the introduction of any significant changes in safety parameters of the MR environment of the site (e.g., adding faster or stronger gradient capabilities or higher RF duty cycle studies) and updated as needed. In this review process, national and international standards and recommendations should be taken into consideration prior to establishing local guidelines, policies, and procedures.
3. Each site will name an MR medical director whose responsibilities will include ensuring that MR safe practice guidelines are established and maintained as current and appropriate for the site. It is the responsibility of the site's administration to ensure that the policies and procedures that result from these MR safe practice guidelines are implemented and adhered to at all times by all of the site's personnel.
4. Procedures should be in place to ensure that any and all adverse events, MR safety incidents, or "near incidents" that occur in the MR site are reported to the medical director in a timely fashion (e.g., within 24 hours or 1 business day of their occurrence) and used in continuous quality improvement efforts. It should be stressed that the Food and Drug Administration states that it is incumbent upon the sites to also report adverse events and incidents to them via their MedWatch program. The ACR supports this requirement and feels that it is in the ultimate best interest of all MR practitioners to create and maintain this consolidated database of such events to help us all learn about them and how to better avoid them in the future [10, 11].

B. Static Magnetic Field Issues: Site Access Restriction

1. Zoning

The MR site is conceptually divided into four Zones (see Figure 1 and Appendix 1):

a. Zone I: This region includes all areas that are freely accessible to the general public. This area is typically outside the MR environment itself and is the area through which patients, health care personnel, and other employees of the MR site access the MR environment.

b. Zone II: This area is the interface between the publicly accessible, uncontrolled Zone I and the strictly controlled Zones III and IV. Typically, patients are greeted in Zone II and are not free to move throughout Zone II at will, but are rather under the supervision of MR personnel (see section B.2.b, below). It is in Zone II that the answers to MR screening questions, patient histories, medical insurance questions, etc. are typically obtained.

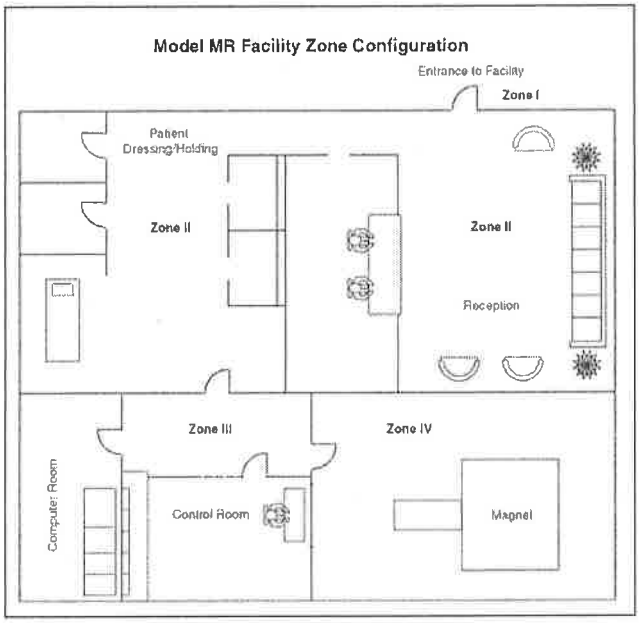

Fig. 1—Idealized sample floor plan illustrates site access restriction considerations. Other MR potential safety issues, such as magnet site planning related to fringe magnetic field considerations, are not meant to be include herein. See Appendix 1 for personnel and zone definitions. Note—In any zone of the facility, there should be compliance with Health Insurance Portability and Accountability Act (HIPAA) regulations in regard to privacy of patient information. However, in Zone III, there should be a privacy barrier so that unauthorized persons cannot view control panels.

c. Zone III: This area is the region in which free access by unscreened non-MR personnel or ferromagnetic objects or equipment can result in serious injury or death as a result of interactions between the individuals or equipment and the MR scanner's particular environment. These interactions include, but are not limited to, those involving the MR scanner's static and time-varying magnetic fields. All access to Zone III is to be strictly restricted, with access to regions within it (including Zone IV, see below) controlled by, and entirely under the supervision of, MR personnel (see section B.2.b, below). Specifically identified MR personnel (typically, but not necessarily only, the MR technologists) are to be charged with ensuring that this MR safe practice guideline is strictly adhered to for the safety of the patients and other non-MR personnel, the health care personnel, and the equipment itself. This function of the MR personnel is directly under the authority and responsibility of the MR medical director or the level 2 MR personnel–designated (see section B.2.b, below) physician of the day for the MR site.

Zone III regions should be physically restricted from general public access by, for example, key locks, passkey locking systems, or any other reliable, physically restricting method that can differentiate between MR personnel and non-MR personnel. The use of combination locks is discouraged as combinations often become more widely distributed than initially intended, resulting in site restriction violations being more likely with these devices. Only MR personnel shall be provided free access, such as the access keys or passkeys, to Zone III.

There should be *no* exceptions to this guideline. Specifically, this includes hospital or site administration, physician, security, and other non-MR personnel (see section B.2.c, below). Non-MR personnel are not to be provided with independent Zone III access until such time as they undergo the proper education and training to become MR personnel themselves. Zone III, or at the very least the area within it wherein the static magnetic field's strength exceeds 5 gauss, should be demarcated and clearly marked as being potentially hazardous.

Because magnetic fields are three-dimensional volumes, Zone III controlled access areas may project through floors and ceilings of MRI suites, imposing magnetic field hazards on persons on floors other than that of the MR scanner. Zones of magnetic field hazard should be clearly delineated, even in typically nonoccupied areas such as rooftops or storage rooms, and access to these Zone III areas should be similarly restricted from non-MR personnel as they would be inside any other Zone III region associated with the MRI suite. For this reason, magnetic field strength plots for all MRI systems should be analyzed in vertical section as well as in horizontal plan, identifying areas above or below, in addition to areas on the same level, where persons may be at risk of interactions with the magnetic field.

d. Zone IV: This area is synonymous with the MR scanner magnet room itself, that is, the physical confines of the room within which the MR scanner is located. Zone IV, by definition, will always be located within Zone III, as it is the MR magnet and its associated magnetic field that generates the existence of Zone III. Zone IV should also be demarcated and clearly marked as being potentially hazardous due to the presence of very strong magnetic fields. As part of the Zone IV site restriction, all MR installations should provide for direct visual observation by level 2 personnel to access pathways into Zone IV. By means of illustration only, the MR technologists would be able to directly observe and control, via line of sight or via video monitors, the entrances or access corridors to Zone IV from their normal positions when stationed at their desks in the scan control room.

Zone IV should be clearly marked with a red light and lighted sign stating, "The Magnet is On." Except for resistive systems, this light and sign should be illuminated at all times and should be provided with a backup energy source to continue to remain illuminated for at least 24 hours in the event of a loss of power to the site.

In case of cardiac or respiratory arrest or other medical emergency within Zone IV for which emergent medical intervention or resuscitation is required, appropriately trained and certified MR personnel should immediately initiate basic life support or CPR as required by the situation *while* the patient is being emergently removed from Zone IV to a predetermined, magnetically safe location. *All* priorities should be focused on stabilizing (e.g., basic life support with cardiac compressions and manual ventilation) and then evacuating the patient as rapidly and safely as possible from the magnetic environment that might restrict safe resuscitative efforts.

Further, for logistical safety reasons, the patient should always be moved from Zone IV to the prospectively identified location where full resuscitative efforts are to continue. (See Appendix 2.)

Quenching the magnet (for superconducting systems only) is not routinely advised for cardiac or respiratory arrest or other medical emergency, since quenching the magnet and having the magnetic field dissipate could easily take more than a minute. Further-

more, as quenching a magnet can theoretically be hazardous, ideally one should evacuate the magnet room, when possible, for an intentional quench. One should rather use that time wisely to initiate life support measures while removing the patient from Zone IV to a location where the strength of the magnetic field is insufficient to be a medical concern. Zones III and IV site access restriction *must* be maintained during resuscitation and other emergent situations for the protection of all involved.

2. MR personnel and non-MR personnel

a. All individuals working within at least Zone III of the MR environment should be documented as having successfully completed at least one of the MR safety live lectures or prerecorded presentations approved by the MR medical director. Attendance should be repeated at least annually, and appropriate documentation should be provided to confirm these ongoing educational efforts. These individuals shall be referred to henceforth as MR personnel.

b. There are two levels of MR personnel:
   1. Level 1 MR personnel: Those who have passed minimal safety educational efforts to ensure their own safety as they work within Zone III will be referred to henceforth as level 1 MR personnel.
   2. Level 2 MR personnel: Those who have been more extensively trained and educated in the broader aspects of MR safety issues, including, for example, issues related to the potential for thermal loading or burns and direct neuromuscular excitation from rapidly changing gradients, will be referred to henceforth as level 2 MR personnel. It is the responsibility of the MR medical director not only to identify the necessary training, but also to identify those individuals who qualify as level 2 MR personnel. It is understood that the medical director will have the necessary education and experience in MR safety to qualify as level 2 MR personnel. (See Appendix 1.)

c. All those not having successfully complied with this MR safety instruction guideline shall be referred to henceforth as non-MR personnel. Specifically, non-MR personnel will be the terminology used to refer to any individual or group who has not within the previous 12 months undergone the designated formal training in MR safety issues defined by the MR safety director of that installation.

3. Patient and non-MR personnel screening

a. *All* non-MR personnel wishing to enter Zone III must first pass an MR safety screening process. Only MR personnel are authorized to perform an MR safety screen before permitting non-MR personnel into Zone III.

b. The screening process and screening forms for patients, non-MR personnel, and MR personnel should be essentially identical. Specifically, one should assume that non-MR personnel, health care practitioners, or MR personnel may enter the bore of the MR imager during the MR imaging process.

   Examples of this might include when a pediatric patient cries for his mother, who then leans into the bore, or when the anesthetist leans into the bore to manually ventilate a patient in the event of a problem.

c. Metal detectors

   The usage in MR environments of conventional metal detectors which do not differentiate between ferrous and nonferromagnetic materials is not recommended. Reasons for this recommendation against conventional metal detector usage include, among others:
   1. They have varied—and variable—sensitivity settings.
   2. The skills of the operators can vary.
   3. Today's conventional metal detectors cannot detect, for example, a 2 × 3 mm, potentially dangerous ferromagnetic metal fragment in the orbit or near the spinal cord or heart.
   4. Today's conventional metal detectors do not differentiate between ferromagnetic and nonferromagnetic metallic objects, implants, or foreign bodies.
   5. Metal detectors should not be necessary for the detection of large metallic objects, such as oxygen tanks on the gurney with the patients. These objects are fully expected to be detected—and physically excluded—during the routine patient screening process.

      However, ferromagnetic detection systems are currently available that are simple to operate, capable of detecting even very small ferromagnetic objects external to the patient, and now, for the first time, differentiating between ferromagnetic and nonferromagnetic materials. While the use of conventional metal detectors is not recommended, the use of **ferromagnetic detection systems** is recommended as an adjunct to thorough and conscientious screening of persons and devices approaching Zone IV. It should be reiterated that their use is in no way meant to replace a thorough screening practice, which rather should be supplemented by their usage.

d. Non-MR personnel should be accompanied by, or under the immediate supervision of and in visual or verbal contact with, one specifically identified level 2 MR person for the entirety of their duration within Zone III or Zone IV restricted regions. However, it is acceptable to have non-MR personnel in a changing room or restroom in Zone III without visual contact as long as the personnel and the patient can communicate verbally with each other.

   Level 1 MR personnel are permitted unaccompanied access throughout Zones III and IV. Level 1 MR personnel are also explicitly permitted to be responsible for accompanying non-MR personnel into and throughout Zone III, excluding Zone IV. However, level 1 MR personnel are *not* permitted to directly admit, or be designated responsible for, non-MR personnel in Zone IV.

   In the event of a shift change, lunch break, etc., no level 2 MR personnel shall relinquish their responsibility to supervise non-MR personnel still within Zone III or Zone IV until such supervision has been formally transferred to another of the site's level 2 MR personnel.

e. Nonemergent patients should be MR safety–screened on site by a minimum of 2 separate individuals. At least one of these individuals should be level 2 MR personnel. At least one of these 2 screenings should be performed verbally or interactively.

   Emergent patients and their accompanying non-MR personnel may be screened only once, providing the screening individual is level 2 MR personnel. There should be no exceptions to this.

f. Any individual undergoing an MR procedure must remove all readily removable metallic personal belongings and devices on or in them (e.g., watches, jewelry, pagers, cell phones, body piercings [if removable], contraceptive diaphragms, metallic

drug delivery patches [see section I, below], cosmetics containing metallic particles [such as eye make-up], and clothing items that may contain metallic fasteners, hooks, zippers, loose metallic components, or metallic threads). It is therefore advisable to require that the patients or research subjects wear a site-supplied gown with no metal fasteners when feasible.

g. All patients and non-MR personnel with a history of potential ferromagnetic foreign object penetration must undergo further investigation prior to being permitted entrance to Zone III. Examples of acceptable methods of screening include patient history, plain X-ray films, prior CT or MR studies of the questioned anatomic area, or access to written documentation as to the type of implant or foreign object that might be present. Once positive identification has been made as to the type of implant or foreign object that is within a patient, best-effort assessments should be made to identify the MR compatibility or MR safety of the implant or object. Efforts at identification might include written records of the results of formal testing of the implant prior to implantation (preferred), product labeling regarding the implant or object, and review of peer-reviewed publications regarding MR compatibility and MR safety testing of the make, model, and type of the object. MR safety testing would be of value only if the object or device had not been altered since such testing results had been published.

   All patients who have a history of orbit trauma by a potential ferromagnetic foreign body *for which they sought medical attention* are to have their orbits cleared either by plain X-ray orbit films (2 views) [12, 13] or by a radiologist's review and assessment of contiguous cut prior CT or MR images (obtained since the suspected traumatic event), if available.

h. Conscious, nonemergent patients and research and volunteer subjects are to complete written MR safety screening questionnaires prior to their introduction to Zone III. Family or guardians of nonresponsive patients or of patients who cannot reliably provide their own medical histories are to complete a written MR safety screening questionnaire prior to their introduction to Zone III. These completed questionnaires are then to be reviewed orally with the patient, guardian, or research subject in their entirety prior to permitting the patient or research subject to be cleared into Zone III.

   The patient, guardian, or research subject as well as the screening MR staff member must both sign the completed form. This form should then become part of the patient's medical record. No empty responses will be accepted—each question *must* be answered with a "yes" or "no" or specific further information must be provided as requested. A sample pre-MR screening form is provided (see Appendix 3). This is the minimum information to be obtained; more may be added if the site so desires.

i. Screening of the patient or non-MR personnel with, or suspected of having, an intracranial aneurysm clip should be performed as per the separate MR safe practice guideline addressing this particular topic (see section M, below).

j. Screening of patients for whom an MR examination is deemed clinically indicated or necessary, but who are unconscious or unresponsive, who cannot provide their own reliable histories regarding prior possible exposures to surgery, trauma, or metallic foreign objects, and for whom such histories cannot be reliably obtained from others:

   1. If no reliable patient metal exposure history can be obtained, and if the requested MR examination cannot reasonably wait until a reliable history might be obtained, it is recommended that such patients be physically examined by level 2 MR personnel. All areas of scars or deformities that might be anatomically indicative of an implant, such as on the chest or spine region, and whose origins are unknown and which may have been caused by ferromagnetic foreign bodies, implants, etc., should be subject to plain-film radiography (if recently obtained plain films or CT or MR studies of such areas are not already available). The investigation described above should be made to ensure there are no potentially harmful embedded or implanted metallic foreign objects or devices. All such patients should also undergo plain film imaging of the skull or orbits and chest to exclude metallic foreign objects (if recently obtained plain films or CT or MR studies of such areas are not already available).
   2. Monitoring of patients in the MR scanner is sometimes necessary. The potential for thermal injury from excessive RF power deposition exists. Sedated, anesthetized, or unconscious patients may not be able to express symptoms of such injury. This potential for injury is greater on especially higher-field whole-body scanners (e.g., 1 Tesla and above). Distortion of the electrocardiogram within the magnetic field makes interpretation of the ECG complex unreliable, even with filtering used by contemporary monitoring systems. However, routine monitoring of heart rate and rhythm may be accomplished using pulse oximetry, which also eliminates the risks of thermal injury from electrocardiography. Patients who require ECG monitoring and who are unconscious, sedated, or anesthetized should be examined after each imaging sequence, with potential repositioning of the ECG leads and any other electrically conductive material with which the patient is in contact. Alternatively, cold compresses or ice packs could be placed upon all necessary electrically conductive material that touches the patient during scanning.

k. Final determination of whether or not to scan any given patient with any given implant, foreign body, etc., is to be made by the level 2 MR personnel–designated attending MR radiologist, the MR medical director, or specifically designated level 2 MR personnel following criteria for acceptability predetermined by the medical director.

   For implants that are strongly ferromagnetic, an obvious concern is that of magnetic translational and rotational forces upon the implant which might move or dislodge the device from its implanted position. If an implant has demonstrated weak ferromagnetic forces on formal testing, it might be prudent to wait several weeks for fibrous scarring to set in, as this may help anchor the implant in position and help it resist such weakly attractive magnetic forces that might arise in MR environments.

   For all implants that have been demonstrated to be nonferrous in nature, however, the risk of implant motion is essentially reduced to those resulting from Lenz's forces alone. These tend to be quite trivial for typical metallic implant sizes of a few centimeters or less. Thus, a waiting period for fibrous scarring to set in is far less important, and the advisability for such a waiting period may well be easily outweighed by the potential clinical benefits of undergoing an MR examination at that time. As always, clinical assessment of the risk–benefit ratio for the par-

ticular clinical situation and patient at hand are paramount for appropriate medical decision making in these scenarios.

It is possible that during the course of an MRI examination an unanticipated ferromagnetic implant or foreign body is discovered within a patient or research subject undergoing the examination. This is typically suspected or detected by means of a sizable field-distorting artifact seen on spin-echo imaging techniques that grows more obvious on longer TE studies and expands markedly on typical moderate or long TE gradient-echo imaging sequences. In such cases, it is imperative that the medical director, safety officer, and/or physician in charge be immediately notified of the suspected findings. This individual should then assess the situation, review the imaging information obtained, and decide what the best course of action might be.

It should be noted that there are numerous potentially acceptable courses that might be recommended which in turn depend upon many factors, including the status of the patient, the location of the suspected ferromagnetic implant/foreign body relative to local anatomic structures, the mass of the implant, etc. Appropriate courses of action might include proceeding with the scan under way, immobilizing the patient and the immediate removal of the patient from the scanner, or other intermediate steps. Regardless of the course of action selected, it is important to note that the forces on the implant will change, and may actually increase, during the attempt to remove the patient from the scanner bore. Further, the greater the rate of motion of the patient/device through the magnetic fields of the scanner bore, the greater the forces acting upon that device will likely be. Thus, it is prudent to ensure that, if at all possible, immobilization of the device during patient extraction from the bore, and the slow, cautious, deliberate rate of extricating the patient from the bore, will likely result in weaker and potentially less harmful forces on the device as it traverses the various static magnetic field gradients associated with the MR imager.

It is also worthy of note that the magnetic fields associated with the MR scanner are distributed throughout space three-dimensionally. Thus, especially for superconducting systems, one should avoid the temptation to have the patient sit up as soon as he or she is physically out of the bore. Doing so may expose the ferrous object to still-significant torque- and translation-related forces despite the patient's being physically outside the scanner bore. It is therefore advisable to continue to extract the patient along a straight line course parallel to the center of the magnet while the patient remains immobilized until they are as far as physically possible from the MR imager itself, before any other patient/object motion vector is attempted or permitted.

l. All non-MR personnel (e.g., patients, volunteers, varied site employees, and professionals) with implanted cardiac pacemakers, autodefibrillators, diaphragmatic pacemakers, or other electromechanically activated devices upon which the non-MR personnel is dependent should be precluded from Zone IV and physically restrained from the 5-gauss line unless specifically cleared in writing by a level 2 MR personnel–designated attending radiologist or the medical director of the MR site. In such circumstances, a specific defending risk–benefit rationale should be provided in writing and signed by the authorizing radiologist.

Should it be determined that non-MR personnel wishing to accompany a patient into an MR scan room require their orbits to be cleared by plain-film radiography, a radiologist must first discuss with the non-MR personnel that plain X-ray films of their orbits are required prior to permitting them access to the MR scan room. Should they still wish to proceed with access to Zone IV or within the 5-gauss line, and should the attending radiologist deem it medically advisable that they do so (e.g., for the care of their child about to undergo an MR study), written informed consent should be provided by these accompanying non-MR personnel prior to their undergoing X-ray examination of their orbits.

m. MR scanning of patients, prisoners, or parolees with metallic prisoner-restraining devices or RF ID or tracking bracelets could lead to theoretic adverse events, including: (1) ferromagnetic attractive effects and resultant patient injury, (2) possible ferromagnetic attractive effects and potential damage to the device or its battery pack, (3) RF interference with the MRI study and secondary image artifact, (4) RF interference with the functionality of the device, (5) RF power deposition and heating of the bracelet or tagging device or its circuitry and secondary patient injury (if the bracelet were in the anatomic volume of the RF transmitter coil being used for imaging). Therefore, when requested to scan a patient, prisoner, or parolee wearing RF bracelets or metallic handcuffs or ankle cuffs, request that the patient be accompanied by the appropriate authorities who can and will remove the restraining device prior to the MR study and be charged with its replacement following the examination.

n. Firefighter, police, and security safety considerations: For the safety of firefighters and other emergent services responding to an emergent call at the MR site, it is recommended that all fire alarms, cardiac arrests, or other emergent service response calls originating from or located in the MR site should be forwarded simultaneously to a specifically designated individual from among the site's MR personnel. This individual should, if possible, be on site prior to the arrival of the firefighters or emergent responders to ensure that they do not have free access to Zone III or Zone IV. The site might consider assigning appropriately trained security personnel, who have been trained and designated as MR personnel, to respond to such calls.

In any case, all MR sites should arrange to prospectively educate their local fire marshals, firefighters' associations, and police or security personnel about the potential hazards of responding to emergencies in the MR suite.

It should be stressed that even in the presence of a true fire (or other emergency) in Zone III or Zone IV, the magnetic fields may be present and fully operational. Therefore, free access to Zone III or Zone IV by firefighters or other non-MR personnel with air tanks, axes, crowbars, other firefighting equipment, guns, etc., might prove catastrophic or even lethal to those responding or to others in the vicinity.

As part of the Zone III and Zone IV restrictions, all MR sites must have clearly marked, readily accessible MR-conditional or MR-safe fire extinguishing equipment physically stored in Zone III or Zone IV. All conventional fire extinguishers and other firefighting equipment not tested and verified safe in the MR environment should be restricted from Zone III.

For superconducting magnets, the helium (and the nitrogen as well, in older MR magnets) is not flammable and does not pose a fire hazard directly. However, the liquid oxygen that can result from the supercooled air in the vicinity of the released

gases might well increase the fire hazard in this area. If there are appropriately trained and knowledgeable MR personnel available during an emergency to ensure that emergency response personnel are kept out of the MR scanner or magnet room and away from the 5-gauss line, quenching the magnet during a response to an emergency or fire should not be a requirement.

However, if the fire is in such a location where Zone III or Zone IV needs to be entered for whatever reason by firefighting or emergency response personnel and their firefighting and emergent equipment, such as air tanks, crowbars, axes, and defibrillators, a decision to quench a superconducting magnet should be *very* seriously considered to protect the health and lives of the emergent responding personnel. Should a quench be performed, appropriately designated MR personnel still need to ensure that *all* non-MR personnel (including and especially emergent response personnel) continue to be restricted from Zones III and IV until the designated MR personnel has personally verified that the static field is either no longer detectable or at least sufficiently attenuated as to no longer present a potential hazard to one moving by it with, for example, large ferromagnetic objects such as air tanks or axes.

For resistive systems, the magnetic field of the MR scanner should be shut down as completely as possible and verified as such prior to permitting the emergency response personnel access to Zone IV. For permanent, resistive, or hybrid systems whose magnetic fields cannot be completely shut down, MR personnel should ideally be available to warn the emergency response personnel that a very powerful magnetic field is still operational in the magnet room.

4. MR personnel screening

All MR personnel are to undergo an MR screening process as part of their employment interview process to ensure their safety in the MR environment. For their own protection and for the protection of the non-MR personnel under their supervision, all MR personnel must immediately report to the MR medical director any trauma, procedure, or surgery they experience or undergo in which a ferromagnetic metallic object or device may have become introduced within or on them. This will permit appropriate screening to be performed on the employee to determine the safety of permitting that employee into Zone III.

5. Device and object screening

Ferrous objects, including those brought by patients, visitors, contractors, etc., should be restricted from entering Zone III, whenever practical.

As part of the Zone III site restriction and equipment testing and clearing responsibilities, all sites should have ready access to a strong handheld magnet (≥ 1000 gauss). This will enable the site to test external, and even some superficial internal, devices or implants for the presence of grossly detectable ferromagnetic attractive forces.

a. All portable metallic or partially metallic devices that are on or external to the patient (e.g., oxygen cylinders) are to be positively identified in writing as ferromagnetic or, alternatively, nonferromagnetic and safe or conditionally safe in the MR environment prior to permitting them into Zone III. For all device or object screening, verification and positive identification should be in writing. Examples of devices that need to be positively identified include fire extinguishers, oxygen tanks, and aneurysm clips.
b. External devices or objects demonstrated to be ferromagnetic and MR unsafe or incompatible in the MR environment may still, under specific circumstances, be brought into Zone III if, for example, they are deemed by MR personnel to be necessary and appropriate for patient care. They should only be brought into Zone III if they are under the direct supervision of specifically designated level 1 or level 2 MR personnel who are thoroughly familiar with the device, its function, and the reason supporting its introduction to Zone III. The safe utilization of these devices while they are present in Zone III will be the responsibility of specifically named level 1 or 2 MR personnel. These devices must be appropriately physically secured or restricted at all times during which they are in Zone III to ensure that they do not inadvertently come too close to the MR scanner and accidentally become exposed to static magnetic fields or gradients that might result in their becoming either hazardous projectiles or no longer accurately functional.
c. Never assume MR compatibility or safety information about the device if it is not clearly documented in writing. All unknown external objects or devices being considered for introduction beyond Zone II should be tested with a strong handheld magnet (≥ 1000 gauss) for ferromagnetic properties before permitting them entry to Zone III. The results of such testing, as well as the date, time, and name of the tester, and methodology used for that particular device, should be documented in writing. If a device has not been tested, or if its MR compatibility or safety status is unknown, it should *not* be permitted unrestricted access to Zone III.
d. All portable metallic or partially metallic objects that are to be brought into Zone IV must be properly identified and appropriately labeled utilizing the current FDA labeling criteria developed by ASTM (American Society for Testing and Materials) International (http://www.astm.org) (see Fig. 2). Those items which are wholly nonmetallic should be identified with a square green "MR safe" label. Items which are clearly ferromagnetic should be identified as "not MR safe" and labeled appropriately with the corresponding round red label with a slash through it. Objects with an "MR conditional" rating should be affixed with a triangular yellow MR conditional label prior to being taken into the scan room/Zone IV.

As noted in the introduction to this section B.5, above, if MR safety data are not prospectively available for a given device, initial testing for the purpose of this labeling is to be accomplished by the site's MR personnel by exposing the metallic object to a handheld magnet (≥ 1000 gauss). If grossly detectable attractive forces are observed between the object being tested or any of its components and the handheld magnet, it is to be labeled with a circular red "not MR safe" label. If no or negligible attractive forces are observed, a triangular yellow "MR conditional" label is to be attached to the object. It is only when the composition of an object and its components are known to be nonmetallic that the green "MR safe" label is to be affixed to a device or object.

Particularly with regard to nonclinical and incidental equipment, current products marketed with ill-defined terminology such as "non-magnetic," or outdated classifications such as "MR-compatible," should not be presumed to conform to a particular current ASTM classification. Similarly, any product marketed as "MR safe" but with metallic construction or components should be treated with suspicion. Objects intended for

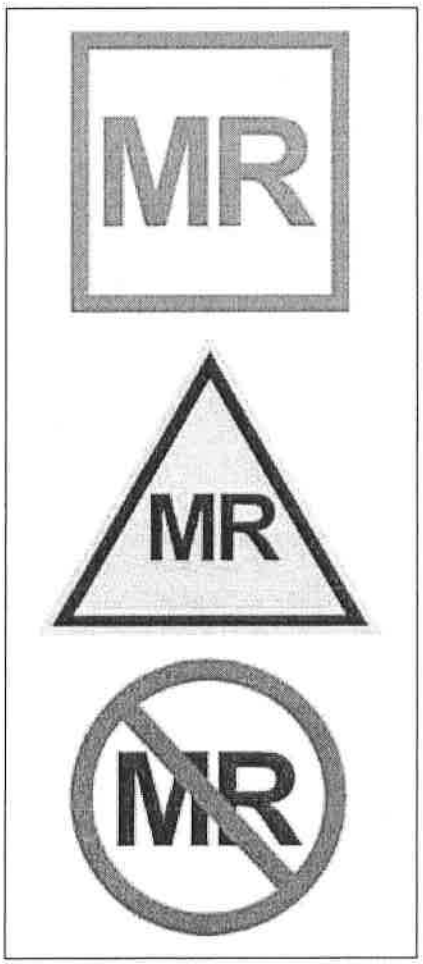

Fig. 2—U.S. Food and Drug Administration labeling criteria (developed by ASTM [American Society for Testing and Materials] International) for portable objects taken into Zone IV. Square green "MR safe" label is for wholly nonmetallic objects, triangular yellow label is for objects with "MR conditional" rating, and round red label is for "not MR safe" objects.

use in Zone IV, including nonclinical incidental products such as stepping stools or ladders, which are not provided with manufacturer or third-party MR safety test results under the new ASTM criteria, should be site tested as described above.

e. Decisions based on published MR compatibility or safety claims should recognize that all such claims apply to specifically tested static field and static gradient field strengths—for example, "MR conditional, having been tested to be safe up to 3.0 Tesla at gradient strengths of 400 G/cm," or "MR conditional, having been tested to be safe up to 1.5 Tesla up to maximum static gradient fields experienced in an unshielded 1.5-Tesla [manufacturer's name] whole-body MR scanner tested 1.5 feet within the bore."

f. It should be noted that alterations performed by the site on MR safe, MR unsafe, and MR conditional equipment or devices may alter the MR safety or compatibility properties of the device. For example, tying a ferromagnetic metallic twisting binder onto a sign labeling the device as MR conditional or MR safe might result in artifact induction—or worse—if introduced into the MR scanner.

Lenz's Forces:

Faraday's law states that a moving or changing magnetic field will induce a voltage in a perpendicularly oriented electrical conductor. Lenz's law builds upon this and states that the induced voltage will itself be such that it will secondarily generate its own magnetic field whose orientation and magnitude will oppose those of the initial time-varying magnetic field that created it in the first place. For example, if an electrical conductor is moved perpendicularly toward the magnetic field, B_0, of an MR scanner, even if this conductor is not grossly ferromagnetic, the motion itself will result in the generation of voltages in this conductor whose magnitude is directly proportional to the rate of motion as well as the spatial gradient of the magnetic field, B_0, through which it is being moved. Conducting objects turning in the static field will also experience a torque due to the induced eddy currents. Lenz's law states that this induced current will in turn create a magnetic field whose orientation will oppose the B_0 magnetic field that created this current.

Thus, moving a large metallic but nonferromagnetic electrical conductor toward the magnet bore will result in the induction of a voltage and associated magnetic field which will orient in such a manner and at such a strength as to oppose the motion of the metallic object into the bore of the MR scanner. If, for example, one tries to move a nonferrous oxygen tank into the bore of an MR scanner, as the scanner bore is approached Lenz's forces will be sufficiently strong to virtually stop forward progress of the tank. Further, the faster one moves the tank into the bore, the greater the opposing force that is created to stop this motion.

This also has potential consequences for large implanted metallic devices such as certain metallic nonferrous infusion pumps. Although they may not pose a projectile hazard, rapid motion of the patient/implant perpendicular to the magnetic field of the MR imager can be expected to result in forces on the implant that would oppose this motion and may likely be detected by the patient. If the patient were to complain of experiencing forces tugging or pulling on the implant, this might bring the patient or health care personnel to erroneously conclude that there were ferrous components to the device, which might lead to cancellation of the examination. Slowly moving such large metallic devices into and out of the bore is a key factor in decreasing any Lenz's forces that might be induced and in decreasing the likelihood of a misunderstanding or an unnecessary study cancellation.

C. MR Technologists

1. MR technologists should be ARRT (American Registry of Radiologic Technologists)–registered technologists (RTs). Furthermore, all MR technologists must be trained as level 2 MR personnel during their orientation prior to being permitted free access to Zone III.
2. All MR technologists will maintain current certification in American Heart Association basic life support at the health care provider level.
3. Except for emergent coverage, there will be a minimum of 2 MR technologists or one MR technologist and one other individual with the designation of MR personnel in the immediate Zone II through Zone IV MR environment. For emergent coverage, the MR technologist can scan with no other individuals in their Zone II through Zone IV environment as long as there is in-house, ready emergent coverage by designated department of radiology MR personnel (e.g., radiology house staff or attending radiologist).

D. Pregnancy-Related Issues

1. Health care practitioner pregnancies

Pregnant health care practitioners are permitted to work in and around the MR environment throughout all stages of their pregnancy [14]. Acceptable activities include, but are not limited to, positioning patients, scanning, archiving, injecting contrast material, and entering the MR scan room in response to an emergency. Although permitted to work in and around the MR environment, pregnant health care practitioners are requested not to remain within the MR scanner bore or Zone IV during actual data acquisition or scanning.

2. Patient pregnancies

Present data have not conclusively documented any deleterious effects of MR imaging exposure on the developing fetus. Therefore, no special consideration is recommended for the first, versus any other, trimester in pregnancy. Nevertheless, as with all interventions during pregnancy, it is prudent to screen women of reproductive age for pregnancy prior to permitting them access to MR imaging environments. If pregnancy is established, consideration should be given to reassessing the potential risks versus benefits of the pending study in determining whether performance of the requested MR examination could safely wait until the end of the pregnancy.

a. Pregnant patients can be accepted to undergo MR scans at any stage of pregnancy if, in the determination of a level 2 MR personnel–designated attending radiologist, the risk–benefit ratio to the patient warrants that the study be performed. The radiologist should confer with the referring physician and document the following in the radiology report or the patient's medical record:
   1. The information requested from the MR study cannot be acquired via nonionizing means (e.g., ultrasonography).
   2. The data are needed to potentially affect the care of the patient or fetus *during* the pregnancy.
   3. The referring physician does not feel it is prudent to wait until the patient is no longer pregnant to obtain these data.

b. MR contrast agents should *not* be routinely provided to pregnant patients. This decision, too, is one that must be made on a case-by-case basis by the covering level 2 MR personnel–designated attending radiologist who will assess the risk–benefit ratio for that particular patient.

   The decision to administer a gadolinium-based MR contrast agent to pregnant patients should be accompanied by a well-documented and thoughtful risk–benefit analysis. This analysis should be able to defend a decision to administer the contrast agent based on overwhelming potential benefit to the patient or fetus outweighing the theoretic but potentially real risks of long-term exposure of the developing fetus to free gadolinium ions.

   Studies have demonstrated that gadolinium-based MR contrast agents pass through the placental barrier and enter the fetal circulation. From there, they are filtered in the fetal kidneys and then excreted into the amniotic fluid. In this location the gadolinium-chelate molecules are in a relatively protected space and may remain in this amniotic fluid for an indeterminate amount of time before finally being reabsorbed and eliminated. As with any equilibrium situation involving any dissociation constant, the longer the chelate molecule remains in this space, the greater the potential for dissociation of the potentially toxic gadolinium ion from its chelate molecule. It is unclear what impact such free gadolinium ions might have if they were to be released in any quantity in the amniotic fluid. Certainly, deposition into the developing fetus would raise concerns of possible secondary adverse effects.

   The risk to the fetus with administration of gadolinium-based MR contrast agents remains unknown and may be harmful.

c. It is recommended that pregnant patients undergoing an MR examination provide written informed consent documenting that they understand the potential risks and benefits of the MR procedure to be performed, are aware of the alternative diagnostic options available to them (if any), and wish to proceed.

E. Pediatric MR Safety Concerns

1. Sedation and monitoring issues

Children form the largest group requiring sedation for MRI, largely because of their inability to remain motionless during scans. Sedation protocols may vary from institution to institution according to the procedures performed (diagnostic vs interventional), the complexity of the patient population (healthy preschoolers vs premature infants), the method of sedation (mild sedation vs general anesthesia), and the qualifications of the sedation provider.

Adherence to standards of care mandates following the sedation guidelines developed by the American Academy of Pediatrics [15, 16], the American Society of Anesthesiologists [17], and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) [18]. In addition, sedation providers must comply with protocols established by the individual state and the practicing institution. These guidelines require the following provisions:

a. Preprocedural medical history and examination for each patient
b. Fasting guidelines appropriate for age
c. Uniform training and credentialing for sedation providers
d. Intraprocedural and postprocedural monitors with adaptors appropriately sized for children (compatible with the magnetic field)
e. Method of patient observation (window, camera)
f. Resuscitation equipment, including oxygen delivery and suction
g. Uniform system of record keeping and charting (with continuous assessment and recording of vital signs)
h. Location and protocol for recovery and discharge
i. Quality assurance program that tracks complications and morbidity.

For the neonatal and the young pediatric population, special attention is needed in monitoring body temperature for both hypo- and hyperthermia in addition to other vital signs [19]. Temperature monitoring equipment that is approved for use in the MR suite is becoming more readily available. Commercially available, MR-approved neonatal isolation transport units and other warming devices are also available for use during MR scans.

2. Pediatric screening issues

Children may not be reliable historians and, especially in cases of older children and teenagers, should be questioned both in the presence of parents or guardians and separately to maximize the possibility that all potential dangers are disclosed. Therefore, it is recommended that children be gowned before entering Zone IV to help ensure that no metallic objects, toys, etc. inadvertently find

their way into Zone IV. Pillows, stuffed animals, and other comfort items brought from home represent real risks and should be discouraged from entering Zone IV. If unavoidable, each such item should be carefully checked with the powerful handheld magnet and perhaps again in the MR scanner prior to permitting the patient to enter Zone IV with the object in order to ensure that it does not contain any objectionable metallic components.

3. MR safety of accompanying family or personnel

Although any age patient might request that others accompany them for their MR examination, this is far more common in the pediatric population. Those accompanying or remaining with the patient should be screened using the same criteria as anyone else entering Zone IV.

In general, it would be prudent to limit accompanying adults to a single individual. Only a qualified, responsible MR physician should make screening criteria exceptions.

Hearing protection and MR safe/MR conditional seating are recommended for accompanying family members within the MR scan room.

F. Time-Varying Gradient Magnetic Field–Related Issues: Induced Voltages

Types of patients needing extra caution:

Patients with implanted or retained wires in anatomically or functionally sensitive areas (e.g., myocardium or epicardium, implanted electrodes in the brain) should be considered to be at higher risk, especially from faster MRI sequences, such as echo-planar imaging (which may be used in such sequences as diffusion-weighted imaging, functional imaging, perfusion-weighted imaging, MR angiographic imaging, etc.). The decision to limit the dB/dt (rate of magnetic field change) and maximum strength of the magnetic field of the gradient subsystems during imaging of such patients should be reviewed by the level 2 MR personnel–designated attending radiologist supervising the case or patient.

G. Time-Varying Gradient Magnetic Field–Related Issues: Auditory Considerations

1. All patients and volunteers should be offered and encouraged to use hearing protection prior to undergoing any imaging in the MR scanners.
2. All patients or volunteers in whom research sequences are to be performed (i.e., MR scan sequences that have not yet been approved by the Food and Drug Administration) are to have hearing protective devices *in place* prior to the initiation of any MR sequences. Without hearing protection in place, MRI sequences that are not FDA-approved should not be performed on patients or volunteers.

H. Time-Varying Radiofrequency Magnetic Field–Related Issues: Thermal

1. All unnecessary or unused electrically conductive materials should be removed from the MR system before the onset of imaging. It is not sufficient to merely to "unplug" or disconnect unused, unnecessary electrically conductive material and leave it within the MR scanner with the patient during imaging. All electrical connections, such as on surface coil leads or monitoring devices, must be visually checked by the scanning MR technologist prior to each use to ensure the integrity of the thermal and electrical insulation.
2. Electrical voltages and currents can be induced in electrically conductive materials that are within the bore of the MR imager during the MR imaging process. This might result in the heating of this material by resistive losses. This heat might be of a caliber sufficient to cause injury to human tissue. Among the variables that determine the amount of induced voltage or current is the consideration that the larger the diameter of the conductive loops, the greater the potential induced voltages or currents, and thus the greater the potential for resultant thermal injury to adjacent or contiguous patient tissue.

   Therefore, when electrically conductive material (wires, leads, implants, etc.) are required to remain within the bore of the MR scanner with the patient during imaging, care should be taken to ensure that no large-caliber electrically conducting loops (including patient tissue; see section H.5, below) are formed within the MR scanner during imaging. Furthermore, it is possible, with the appropriate configuration, lead length, static magnetic field strength, and other settings, to introduce resonant circuitry between the transmitted RF power and the lead. This could result in very rapid and clinically significant lead heating, especially at the lead tips, in a matter of seconds to a magnitude sufficient to result in tissue thermal injury or burns. This can also theoretically occur with implanted leads or wires, even when they are not connected to any other device at either end. For illustration, the FDA has noted several reports of serious injury, including coma and permanent neurologic impairment, in patients with implanted neurologic stimulators who underwent MR imaging examinations. The injuries in these instances resulted from heating of the electrode tips [20, 21].

   Further, it is entirely possible for a lead or wire to demonstrate no significant heating while undergoing MR imaging examinations at 1.5 Tesla, yet demonstrate clinically significant and potentially harmful degrees of heating within seconds at, for example, 3 Tesla. It has also been demonstrated that leads may show no significant heating at 3 Tesla yet may rapidly heat to hazardous levels when undergoing MR imaging at, for example, 1.5 Tesla (personal observation, MR safety testing, E. Kanal, MD, University of Pittsburgh Medical Center MR Research Center, 8/28/05). Thus, at no time should a label of "MR conditionally safe for thermal issues at [a given field strength]" be applied to any field strength, higher or lower, other than the specific one at which safety was demonstrated.

   Thus, exposure of electrically conductive leads or wires to the RF transmitted power during MR scanning should only be performed with caution and with appropriate steps taken to ensure significant lead or tissue heating does not result (see section H.9, below).
3. When electrically conductive materials are required to be within the bore of the MR scanner with the patient during imaging, care should be taken to place thermal insulation (including air, pads, etc.) between the patient and the electrically conductive material, while simultaneously attempting (as much as feasible) to keep the electrical conductor from directly contacting the patient during imaging. It is also appropriate to try to position the leads or wires as far as possible from the inner walls of the MR scanner if the body coil is being used for RF transmission. When it is necessary that electrically conductive leads directly contact the patient during imaging, consideration should be given to prophylactic application of cold compresses or ice packs to such areas.
4. Depending on specific magnet designs, care may be needed to ensure that the patient's tissue(s) do not directly come into contact with the inner bore of the MR imager during the MRI process. This

is especially important for several higher-field MR scanners. The manufacturers of these devices provide pads and other such insulating devices for this purpose, and manufacturer's guidelines should be strictly adhered to for these units.

5. It is important to ensure the patient's tissues do not form large conductive loops. Therefore, care should be taken to ensure that the patient's arms or legs are not positioned in such a way as to form a large-caliber loop within the bore of the MR imager during the imaging process. For this reason, it is preferable that patients be instructed not to cross their arms or legs in the MR scanner. We are also aware of unpublished reports of thermal injuries that seem to have been associated with skin folds, such as in the region of the inner thighs. While the cause of this is not yet fully understood, it might be prudent to consider ensuring that skin folds and other such examples of tissue-to-tissue contact are minimized or eliminated in the region undergoing radiofrequency energy irradiation.
6. Skin staples and superficial metallic sutures: Patients requested to undergo MR studies in whom there are skin staples or superficial metallic sutures (SMS) may be permitted to undergo the MR examination if the skin staples or SMS are not ferromagnetic and are not in the anatomic volume of RF power deposition for the study to be performed. If the nonferromagnetic skin staples or SMS are within the volume to be RF-irradiated for the requested MR study, several precautions are recommended.
   a. Warn the patient and make sure that they are especially aware of the possibility that they may experience warmth or even burning along the skin staple or SMS distribution. The patient should be instructed to report immediately if they experience warmth or burning sensations during the study (and not, for example, wait until the "end of the knocking noise").
   b. It is recommended that a cold compress or ice pack be placed along the skin staples or SMS if this can be safely clinically accomplished during the MRI examination. This will help to serve as a heat sink for any focal power deposition that may occur, thus decreasing the likelihood of a clinically significant thermal injury or burn to adjacent tissue.
7. For patients with extensive or dark tattoos, including tattooed eyeliner, in order to decrease the potential for RF heating of the tattooed tissue, it is recommended that cold compresses or ice packs be placed on the tattooed areas and kept in place throughout the MRI process if these tattoos are in the volume in which the body coil is being used for RF transmission. This approach is especially appropriate if fast spin-echo (or other high RF duty cycle) MRI sequences are anticipated in the study. If another coil is being used for RF transmission, a decision must be made if high RF transmitted power is to be anticipated by the study protocol design. If so, then the above precautions should be followed. Additionally, patients with tattoos that had been placed within 48 hours prior to the pending MR examination should be advised of the potential for smearing or smudging of the edges of the freshly placed tattoo.
8. In the unconscious or unresponsive patient, all attached leads that will be in or partly in the volume undergoing RF irradiation should be covered with a cold compress or ice pack at the lead attachment site for the duration of the MR study.
9. As noted above, it has been demonstrated that resonant circuitry can be established during MRI between the RF energies being transmitted and specific lengths of long electrically conductive wires or leads, which can thus act as efficient antennae. This can result in heating of the tips of these wires or leads to temperatures in excess of 90°C in a few seconds. Therefore, patients in whom there are long electrically conductive leads, such as Swan-Ganz thermodilution cardiac output–capable catheters or Foley catheters with electrically conductive leads, should be considered at risk for MR studies if the body coil is to be used for RF transmission over the region of the electrically conductive lead. This is especially true for higher-field systems and for imaging protocols utilizing fast spin-echo or other high-RF duty cycle MRI sequences. Each such patient should be reviewed and cleared by an attending level 2 radiologist and a risk–benefit ratio assessment performed prior to permitting them access to the MR scanner.
10. The potential to establish substantial heating is itself dependent on multiple factors, including, among others, the static magnetic field strength of the MR scanner (as this determines the transmitted radiofrequencies [RF] at which the device operates) and the length, orientation, and inductance of the electrical conductor in the RF-irradiated volume being studied. *Virtually any lead lengths can produce substantial heating.* Innumerable factors can affect the potential for tissue heating for any given lead. It is therefore critical to recognize that of all electrically conductive implants, it is specifically wires, or leads, that pose the greatest potential hazard for establishing substantial power deposition/heating considerations.

    Another important consideration is that as a direct result of the above, it has already been demonstrated in vitro that heating of certain implants or wires may be clinically insignificant at, for example, 1.5 Tesla but quite significant at 3.0 Tesla. However, it has also been demonstrated that specific implants might show no significant thermal issues or heating at 3.0 Tesla, *but may heat to clinically significant or very significant levels in seconds at, for example, 1.5 Tesla.* Thus, it is important to follow established product MR safety guidelines carefully and precisely, applying them to, and only to, the static magnetic field strengths at which they had been tested. MR scanning at either stronger and/or weaker magnetic field strengths than those tested may result in significant heating where none had been observed at the tested field strength(s).

I. Drug Delivery Patches and Pads

Some drug delivery patches contain metallic foil. Scanning the region of the metallic foil may result in thermal injury [22]. Since removal or repositioning can result in altering of patient dose, consultation with the patient's prescribing physician would be indicated in assessing how to best manage the patient. If the metallic foil of the patch delivery system is positioned on the patient so that it is in the volume of excitation of the transmitting RF coil, the case should be specifically reviewed with the radiologist or physician covering the patient. Alternative options may include placing an ice pack directly on the patch. This solution may still substantially alter the rate of delivery or absorption of the medication to the patient (and be less comfortable to the patient, as well). This ramification should therefore not be treated lightly, and a decision to proceed in this manner should be made by a knowledgeable radiologist attending the patient and with the concurrence of the referring physician as well.

If the patch is removed, a specific staff member should be given responsibility for ensuring that it is replaced or repositioned.

J. Cryogen-Related Issues

1. For superconducting systems, in the event of a system quench, it is imperative that all personnel and patients be evacuated from the MR

scan room as quickly as safely feasible and that the site access be immediately restricted to all individuals until the arrival of MR equipment service personnel. This is especially so if cryogenic gases are observed to have vented partially or completely into the scan room, as evidenced in part by the sudden appearance of white "clouds" or "fog" around or above the MR scanner. As noted in section B.3.n above, it is especially important to ensure that all police and fire response personnel are restricted from entering the MR scan room with their equipment (axes, air tanks, guns, etc.) until it can be confirmed that the magnetic field has been successfully dissipated, because there may still be a considerable static magnetic field present despite a quench or partial quench of the magnet [23].

2. It should be pointed out that room oxygen monitoring was discussed by the MR Blue Ribbon Panel and rejected at this time because the present oxygen monitoring technology was considered by industry experts not to be sufficiently reliable to allow continued operation during situations of power outages, etc.

K. Claustrophobia, Anxiety, Sedation, Analgesia, and Anesthesia

Adult and pediatric patient anxiolysis, sedation, analgesia, and anesthesia for any reason should follow established ACR [24, 25], American Society of Anesthesiologists (ASA) [26–29], and JCAHO standards [29].

L. Contrast Agent Safety

1. Contrast agent administration issues

No patient is to be administered prescription MR contrast agents without orders from a duly licensed physician. Intravenous injection–qualified MR technologists may start and attend to peripheral IV access lines if they have undergone the requisite site-specified training in peripheral IV access and have demonstrated and documented appropriate proficiency in this area. IV-qualified MR technologists may administer FDA-approved gadolinium-based MR contrast agents via peripheral IV routes as a bolus or as a slow or continuous injection as directed by the orders of a duly licensed site physician.

Administration of these agents is to be performed according to the ACR policy. The ACR approves of the injection of contrast material and diagnostic levels of radiopharmaceuticals by certified and/or licensed radiologic technologists and radiologic nurses under the direction of a radiologist or his or her physician designee who is personally and immediately available, if the practice is in compliance with institutional and state regulations. There must also be prior written approval by the medical director of the radiology department or service of such individuals. Such approval process must follow established policies and procedures, and the radiologic technologists and nurses who have been so approved must maintain documentation of continuing medical education related to materials injected and to the procedures being performed [30].

2. Prior contrast agent reaction issues

a. According to the ACR *Manual on Contrast Media* [31], adverse events after intravenous injection of gadolinium seem to be more common in patients who had previous reactions to an MR contrast agent. In one study, 16 (21%) of 75 patients who had previous adverse reactions to MR contrast agents reacted to subsequent injections of gadolinium [31]. Patients with asthma also seem to be more likely to have an adverse reaction to the administration of a gadolinium-based MR contrast agent. Patients with allergies also seemed to be at increased risk (~2.0–3.7 times, compared with patients without allergies). Patients who have had adverse reactions to iodinated contrast media are more than twice as likely to have an adverse reaction to gadolinium (6.3% of 857 patients) [31].

b. At present, there are no well-defined policies for patients who are considered to be at increased risk for having an adverse reaction to MR contrast agents. However, the following recommendations are suggested: Patients who have previously reacted to one MR contrast agent can be injected with another agent if they are restudied, and at-risk patients can be premedicated with corticosteroids and, occasionally, antihistamines [31].

c. All patients with asthma, a history of allergic respiratory disorders, prior iodinated or gadolinium-based contrast reactions, etc., should be followed more closely as they are at a demonstrably higher risk of adverse reaction.

3. Renal disease, gadolinium-based MR contrast agents, and nephrogenic systemic fibrosis (NSF)

a. Overview:

It has been recently noted that over a 4-year period, 20 patients in Denmark and five in Austria developed a very rare disease that is seen only in patients with severely impaired renal function [32, 33]. Each of these patients had been administered Omniscan (gadodiamide, GE Healthcare), a gadolinium-based MR contrast agent (GBMCA), for an MR imaging or angiographic examination within a few weeks or months prior to the onset of the disease. Roughly 17,500 patients are examined using Omniscan in Denmark each year. Since January 2002, about 400 patients with severely impaired renal function had been examined, of which 20, or 5%, to whom Omniscan had been administered, eventually were diagnosed with this disease in that country.

The disease in question, originally known as nephrogenic fibrosing dermopathy (NFD) and now more widely recognized as nephrogenic systemic fibrosis (NSF), was only first observed in 1997 and formally described in 2000 [34]. It is associated with increased tissue deposition of collagen, often resulting in thickening and tightening of the skin (usually involving predominantly the distal extremities but occasionally also the trunk) and fibrosis that may involve other parts of the body, including the diaphragm, heart, lung, pulmonary vasculature, and skeletal muscles. There is no definitive cure, although some anecdotal reports exist of at least partial responses to various therapies such as plasmapheresis, extracorporeal photopheresis, and thalidomide. There are some data that suggest slowing or even reversal of the disease symptoms may accompany improvements in renal function (especially transplantation). The disease is progressive and can be fulminant in approximately 5% of cases and can even be associated with a fatal outcome. It is generally seen in middle-aged patients but has also been seen in the elderly as well as the pediatric population [35, 36]. There may be a special predilection for patients with concurrent hepatic disease, but this is not yet clearly established [37, 38].

A central registry for NSF patients is maintained at Yale University by Dr. Shawn Cowper, one of the physicians who originally described this disease [39]. At the time of this writing (1/25/07), virtually all reg-

istry cases in which records can be located have at least one known exposure to gadolinium within a few days to months prior to the development of clinical symptoms [37, verbal communication with Dr. Cowper, December 2006].

b. The association with gadolinium-based MR contrast agents (GBMCAs):

Besides the initial reports noted above, in August 2, 2006, researchers from the Copenhagen University Hospital in Denmark published in the *Journal of the American Society of Nephrology* [40] the results of their review of all 13 confirmed cases of NSF, in which they found that all 13 had received Omniscan 2–75 days (median, 25 days) prior to the development of NSF. To quote from their manuscript, "No other exposure/event than gadodiamide that was common to more than a minority of the patients could be identified. These findings indicate that gadodiamide plays a causative role in nephrogenic systemic fibrosis."

In that article, they also reported that these 13 patients with confirmed NSF were among roughly 370 severe renal disease patients whom they had tracked who had undergone gadodiamide exposure/administration for an MR examination, whereas none of > 430 patients with severe renal disease who had not received a GBMCA developed NSF.

Although this association was initially reported between Omniscan and NSF, there are now multiple submitted MedWatch cases [11] that allege that diagnoses of NSF followed intravenous administration of Magnevist (gadopentetate dimeglumine, Schering) as well as intravenous administration of OptiMARK (gadoversetamide, Mallinckrodt), which are other chelates of GBMCAs. It is clear that the vast majority (≈ 90%) of known cases at this time seem to be clearly associated with Omniscan to a degree that is out of proportion to the relative market shares for these agents [41, 42]. As of January 17, 2007, of the > 100 cases of NSF reported to the FDA MedWatch reporting system, 85 are Omniscan-associated, 21 are Magnevist-associated, six are OptiMARK-associated, none are associated with ProHance (gadoteridol, Bracco Diagnostics), and one is associated with MultiHance (gadobenate dimeglumine, Bracco Diagnostics) (although this same patient also received Omniscan 5 days after their MultiHance MR examination, and subsequently developed NSF) (personal communication, Dr. Melanie Blank, FDA, January 18, 2007). It is also important to recognize the substantial lack of scientific process inherent in the MedWatch reporting system, whose self-reported data can be used at best as general-trend-indicating and typically not for more specific analyses. Nevertheless, the data support the FDA's concern that this association may exist for the administration of other, or perhaps any of the other, FDA-approved GBMCAs and the subsequent development of NSF. Although there is evidence associating the development of NSF in renal failure patients with only some, but not all, of the FDA-approved GBMCAs to date, prudence dictates that at this time similar concerns be applied to all GBMCAs in this regard until more definitive information is forthcoming on this issue.

c. Causation?

There is a conjecture that suggests that if a causative relationship exists, it may be secondary to accumulation of the gadolinium chelate or free gadolinium in the dependent subcutaneous tissues of the lower and upper extremities (where the disease seems to most often initially manifest itself). Further, if there is free gadolinium released in any quantity, studies have suggested that it may accumulate in and bind to bone [43]. Very recent initial reports have apparently demonstrated the presence of gadolinium in the biopsies of tissues of NSF patients [44, 45]. In one control individual without NSF, no gadolinium was found using the same electron dispersion spectroscopy technique.

It should also be added that the very visualization of gadolinium in the scanning electron micrographs (SEM) noted in these two recent publications [44, 45] itself is strong evidence that dissociation of the gadolinium from its chelate has occurred. This can be related to the observation that in the process of preparing the tissue for SEM, water-soluble forms of gadolinium would have likely been removed from the specimen, leaving only the insoluble forms to precipitate out (verbal communication, Michael Tweedle, Bracco Diagnostics, January 2007, and Hanns-Joachim Weinmann, Bayer Schering Pharma, January 19, 2007). These precipitates are likely to be largely gadolinium phosphates (verbal communication, Hanns-Joachim Weinmann, January 19, 2007), but this is neither definite nor universally established.

Additionally, it has been noted by several investigators that the development of NSF seemed to most commonly (although not exclusively) follow high-dose administration of gadolinium-based MR contrast agents. This dose-response observation also suggests a possible etiologic role of these agents in the development of NSF in these patients [37].

Although a definitive causal relationship between GBMCA administration to severe renal disease patients and the development of NSF has not been absolutely established, it certainly does appear that gadolinium administration is quite likely a necessary factor in the development of NSF at this time. If a causative role is postulated or even demonstrated, it is unclear whether the causative agent is released free gadolinium, prolonged exposure to abnormally high doses of the gadolinium-plus-chelate molecule, the chelate itself, or some combination of the above with other factors that might be relatively unique to the biochemical milieu of the patient with severe renal failure. This is supported in part by the observation that in several of the publications, including the initial report from the Danish Medicines Agency [33, 37], the incidence of developing NSF in patients with severe or end-stage renal disease after being administered Omniscan appears to be roughly only 3–5%.

There are early data that suggest that elevated levels of phosphate, iron, zinc, or copper [46] or the presence of Fosrenol (lanthanum carbonate, Shire) might serve as efficient competitors for the "attention" of the chelate molecule, so to speak, and increase the concentration of free gadolinium (Gd^{3+}) in the patient, which might therefore increase the potential of the patient to develop NSF. A history of multiple prior GBMCA administrations also seems to be associated with an increased incidence of subsequent development of NSF.

d. Gadolinium toxicity:

Free gadolinium ion exists most commonly in a 3^+ charged form that inhibits those chemical processes that depend upon the influx of calcium (2^+) ions, such as cardiac and skeletal muscle, neurologic discharge, normal coagulation pathways, some enzymatic reactions, etc.

e. FDA guidance:

On December 22, 2006, the FDA issued an update [47] to their earlier June 9, 2006, public health advisory (PHA) [48]. This new

version has significantly changed from the prior one in several areas. One of these modifications includes the fact that the new version now includes wording that recommends caution in administering GBMCAs to patients with moderate to end-stage renal disease as well as consideration of providing hemodialysis treatment immediately after administration of this agent for patients in this category of renal disease who receive these agents. (The prior advisory recommended caution, especially in patients with end-stage renal disease, with glomerular filtration rates of < 15 mL/min/m^2 [48].) Quoting from this more recent advisory [47]:

> *When a patient with moderate to end-stage kidney disease needs an imaging study, select imaging methods other than MRI or MRA with a gadolinium-based contrast agent for the study whenever possible. If these patients must receive a gadolinium-based contrast agent, prompt dialysis following the MRI or MRA should be considered.*

Average excretory rates of gadolinium were 78%, 96%, and 99% in the first to third hemodialysis sessions, respectively, in end-stage renal disease patients who received Magnevist [49]. One study has found that the mean half-life of gadodiamide is 1.3 hours in healthy volunteers, 34.3 hours in patients with a glomerular filtration rate (GFR) range of 2–10 mL/min/m^2, 2.6 hours in hemodialysis patients, and 52.7 hours in peritoneal dialysis patients [50]. It is also known that different hemodialysis membranes have been demonstrated to vary in their effectiveness at clearing the administered GBMCA [51].

It should be pointed out that virtually all present data seem to indicate that the vast majority of NSF patients to date had either severe or end-stage renal disease at the time of diagnosis or administration of the GBMCA, with most already being on dialysis. The official National Kidney Foundation staging system classifies patients with glomerular filtration rates between 30 and 59 mL/min/1.73 m^2 as having stage 3 or moderate chronic kidney disease (CKD), between 15 and 29 mL/min/1.73 m^2 as stage 4 or severe CKD, and those with GFR < 15 mL/min/1.73 m^2 or on dialysis as having stage 5 or end-stage CKD. More than one of four adults over age 70 has a GFR of < 60 mL/min/1.73 m^2, and roughly 7.7 million Americans have a GFR between 30 and 60 mL/min/1.73 m^2 [52]. Based on NHANES III 1988–1994 (the Third National Health and Nutrition Examination Survey of the CDC) [53], the prevalence of a GFR < 60 mL/min/m^2 in US adults ≥ 20 years of age was 8.0%, or more than one of every 13 adults. By age 70, the normal mean value is approximately 70 mL/min/1.73 m^2. For adults age 70 and older, the prevalence of GFR < 60 mL/min/1.73 m^2 is roughly 26%, or more than one in four. Finally, the normal GFR for neonates ≤ 8 weeks of age is < 65 mL/min/1.73 m^2 [54]. Therefore, an advisory statement worded in this manner might result in exposing patients to the potentially greater risks of hemodialysis or in withholding contrast enhancement for their studies. Since the elderly population are among the greatest users of MRI today, this advisory is especially of concern.

f. Other guidance resources:

An overview of this disease, as well as our recommendations for guidelines regarding NSF, renal disease patients, and gadolinium-based MR contrast agent administration, was accepted for publication in *Radiology* and is already available for download from *Radiology*'s online site [55].

The European Agency for the Evaluation of Medicinal Products (EMEA) has recently issued a recommendation [56] to consider the administration of Omniscan (and OptiMARK, although the latter is not licensed in Europe) as contraindicated in patients with severe renal disease (GFR < 30 mL/min/1.73m^2) or those who have had or will be undergoing a liver transplant. They also warn that for children up to 1 year of age, because their kidneys are immature, one should be most cautious about administering Omniscan (or OptiMARK). For the other non-Omniscan gadolinium-based MR contrast agents (GBMCAs), they advise simply that there is a possibility of NSF resulting with some GBMCAs in patients with severe renal disease. The European Pharmacovigilance Working Party (PhVWP) and the United Kingdom Commission on Human Medicines (CHM) do not recommend dialysis after administration of GBMCAs, even for hemodialysis patients [56].

As noted above, the FDA continues to recommend considering immediate hemodialysis for any patient with moderate, severe, or end-stage renal disease receiving any GBMCA [47].

g. Recommendations:

At this stage, the following guidelines are recommended when considering administering a GBMCA to patients with renal failure/disease:

The development of NSF in patients with renal disease has followed the administration of some, but not all, of the FDA-approved GBMCAs. To date, the development of NSF has been associated with the isolated prior administration of—especially, and clearly predominantly—Omniscan (at rates that exceed those associated with simple market share), but also Magnevist and OptiMARK. Nevertheless, it is thought to be appropriate to assume for now that a potential association might exist for all five FDA-approved gadolinium-based MR contrast agents until there are more definitive data to suspect otherwise.

At this time, no special treatment or handling is recommended for kidney disease patients with stage 1 or 2 chronic kidney disease (defined as presence of kidney damage with GFR > 90 mL/min/1.73 m^2 or GFR between 60 and 89 mL/min/1.73 m^2, respectively). The only exception to this is that patients with any level of renal disease should not receive Omniscan for their contrast-enhanced MR examinations. This is an opinion shared by others [57] and seems prudent for all renal disease patients.

Prospectively checking patient renal function, serum creatinine level, or glomerular filtration rate prior to accepting a patient for an MR imaging or angiographic examination is specifically not required. Among the reasons for this is that roughly 90% of NSF patients seem to already be on dialysis and the majority of the remainder seem to be stage 5 or stage 4. Add to this the fact that one could avoid administering any of the agents with which NSF has been most strongly associated, and the fact that even in patients with severe or end-stage renal disease the incidence of developing NSF seems to be around 3–5%. Therefore, specific prospective hematologic screening is not felt to be warranted. Instead, it is recommended that all requests for MR be prescreened, with an additional question inquiring about the presence of a history of "kidney disease or dialysis." If the disease is present but quite mild (stages 1 or 2), modification of how the study should be performed (relative to a patient with no renal disease) does not appear to be indicated except for the avoidance of Omniscan. Conversely, if the disease is present and severe or end-stage in nature, the patient will often be aware of this level of kidney disease and will likely be under

physician care for this condition. *The American Journal of Kidney Diseases* states [54]: "In general, patients with GFR <30 mL/min/1.73 m^2 should be referred to a nephrologist." Thus, selecting patients with a GFR threshold of roughly 30 mL/min/1.73 m^2 or already on dialysis (i.e., stages 4 and/or 5) as the level for which special consideration (including possibly hemodialysis) should be given, might represent a medically reasonable approach to, and compromise on, this issue. For patients with stage 3 CKD, the potential risks associated with withholding an MR imaging or angiographic examination could outweigh the potential risk of developing NSF, given the very few number of patients with putative GFR < 60 mL/min/m^2 who have been reported to have developed NSF. Further data are clearly needed to clarify the potential risk for stage 3 CKD patients given the few cases reported and the large number of patients with stage 3 CKD and who are predominantly older than age 70 who would be affected.

For all patients with stage 3, 4, or 5 kidney disease or those with acute kidney injury (AKI), it is recommended that one consider refraining from administering any GBMCAs unless a risk–benefit assessment for that particular patient indicates that the benefit of doing so clearly outweighs the potential risk(s). Similar reasoning applies equally to patients with protected regions which the gadolinium chelate might enter but from which it might not be readily cleared. An example of such a space is the amniotic fluid, in which these contrast agents can accumulate shortly after intravenous administration (personal observation and verbal communication, Emanuel Kanal, 1988).

When risk–benefit assessments warrant administration of a GBMCA to patients with stages 3–5 renal disease (moderate to end-stage) or AKI, consideration should be given to administering the lowest dose that would provide the diagnostic benefit being sought, with a half-dose, if clinically acceptable, being considered the default standard dose for such patients. The study should be monitored during its execution and prior to contrast administration to ensure that the administration of the GBMCA is still deemed necessary and indicated at that time. Postponing the examination in patients with AKI until renal function has recovered should also be considered if clinically feasible.

Standard medical practice dictates that for all patients who receive a contrast agent, the type, dose, and route of administration are to be documented in a physician order and in the report. However, patients with moderate to end-stage (stages 3–5) renal disease who are to undergo contrast-enhanced MR imaging examinations of any kind must have a written order to this effect for this agent from the radiologist approving the examination. This order must arise explicitly from the radiologist and NOT from either a referring physician or an MR imaging protocol standing order. The name of the patient, the name and specific brand of GBMCA, dose, route, and rate of administration should all be explicitly specified on the order, along with the date and signature of the requesting radiologist.

Prospective documentation of a risk–benefit assessment for each such patient is considered advisable. It is recommended that all patients identified as having moderate to end-stage (stages 3–5) kidney disease in whom a GBMCA is to be administered provide informed consent when practical, which includes a review of known risks and benefits as well as the possible availability of alternative imaging methods, if any.

As noted above, early data suggest that elevated levels of phosphate, iron, zinc, or copper might serve as efficient competitors for the "attention" of the chelate molecule [46]. These might therefore result in increased levels of free gadolinium (Gd^{3+}) ion in the patient, which might in turn increase the potential of the patient to develop NSF. Other cations such as lanthanum, now used as lanthanum carbonate (Fosrenol) for phosphorus binding in end-stage renal disease patients, could also present similar transmetallation and free gadolinium concerns. A history of multiple prior GBMCA administrations or hepatorenal disease also seems to be associated with an increased incidence of subsequent development of NSF. The existence of acidosis or active inflammatory and/or thrombotic processes as possible increased risk factors has been entertained but has not been reproducibly established at this point. This information should be taken into account during the risk–benefit assessment of each individual patient.

For administration of GBMCAs to patients on hemodialysis, the patient is to be transported to hemodialysis immediately upon the termination of the MR imaging examination. Arrangements should be made with the treating dialysis centers to provide them with as much notice as possible prior to the arrival of that patient for hemodialysis. It is recommended that hemodialysis be initiated no later than 2 hours following the administration of the GBMCA. This applies equally to emergent or urgent gadolinium chelate administration to these patients and to inpatients as well as outpatients. An additional hemodialysis session should be considered within 24 hours of this first contrast-enhanced treatment session for the reasons noted above.

For administration to patients on chronic ambulatory peritoneal dialysis (CAPD) or continuous cycler-assisted peritoneal dialysis (CCPD) (also known as automated peritoneal dialysis, or APD), there appears to be strong reason to hesitate to administer these agents. As noted above, this process of dialysis seems to be relatively ineffective at clearing the gadolinium from the body. Thus, special caution should be exercised when deciding whether a peritoneal dialysis patient should receive gadolinium-based MR contrast agents. If it is decided that they should be administered such agents, administration of the lowest reasonable dose is strongly recommended. In the past, it had been recommended that the patient avoid periods of a dry abdomen (i.e., no dialysate in the peritoneal cavity) and that the patient be advised to begin additional dialysis self-treatments or CCPD treatments immediately upon the termination of the MR examination in which the GBMCA was administered. These suggestions seemed prudent, although the efficacy of these recommendations had not been established. However, in light of the near-total apparent ineffectiveness of peritoneal dialysis at clearing the gadolinium from the body, it may well be worth considering immediate initiation of hemodialysis in peritoneal dialysis patients who receive even a low dose of a GBMCA, or not administering the agent if clinically feasible. Investigations are ongoing at this time to attempt to assess prevalence rates of NSF in peritoneal dialysis versus hemodialysis patients, although at this time it is too early for definitive conclusions.

Historically, as a result of the high atomic number associated with GBMCAs, these agents have occasionally been administered to (especially renal failure) patients in an off-label manner for such X-ray-based diagnostic tests as conventional angiography (including access angiography and fistulography) and even CT scanning. The rationale behind this practice was to avoid the administration of iodinated contrast agents to these patients and to decrease the incidence or likelihood of the development of contrast-induced nephropathy. In an attempt to prevent inadvertent GBMCA administration to renal disease patients by nonradiologists (who may at this point still not be fully aware of the issues and risks associated with GBMCAs), for now it is thought pru-

dent to ensure that all GBMCAs are to be administered only by radiologists. If there is a request for a GBMCA to be administered by a nonradiologist to a patient for an off-label use, such as intraarterial administration for vascular assessment in renal failure patients, this must be made in the form of a written order. All such requests must be prospectively reviewed and approved by either a radiologist or a pharmacist knowledgeable in the issues raised above, a risk–benefit assessment should be prospectively performed, and, where practical, informed consent should be provided by the patient.

For patients in whom a diagnosis of NSF has already been established, it might be appropriate to consider avoiding entirely any administration of a gadolinium-based MR contrast agent.

For patients not already on hemodialysis, the FDA's December 22, 2006 advisory [47] notwithstanding, the decision to initiate hemodialysis following gadolinium administration should not be taken lightly. The vast majority of NSF cases developed in patients with severe or end-stage renal disease, and most were already dialysis patients. The numbers of patients with moderate, as opposed to severe or end-stage, renal disease who have been diagnosed with NSF is exceedingly small, if they exist at all. At this time, it seems reasonable to assume that as the renal function/GFR decreases from 60 mL/min/m^2 through 30 mL/min/m^2, 15 mL/min/m^2, and below, the greater the concern and the greater the likelihood of subsequent NSF development. Therefore, we think that at the present time insufficient data exist to advise consideration for hemodialysis in this population of patients with moderate chronic kidney disease (stage 3) in the same manner or same perceived risk as those with severe or end-stage renal disease (stages 4 and 5). The risks of initiating hemodialysis must be seriously weighed against those of developing NSF in each particular case before a decision is made one way or the other. Finally, withholding clinically indicated GBMCAs can also be associated with its own risks, which should be considered in the decision-making process for all patients with kidney disease.

Should a new diagnosis of NSF be made, it is recommended that the FDA be notified through their MedWatch program (http://www.fda.gov/medwatch/) [11] or by phone (1-800-FDA-1088), and that the international NSF registry at Yale University be notified as well (http://www.icnfdr.org) [39] to ensure that each database is kept as current as possible on this rapidly changing environment.

In the weeks and months to come, it is anticipated that there will be much further study of this issue, and that more information will be forthcoming that will hopefully shed more light on this important issue [56].

M. Patients in Whom There Are or May Be Intracranial Aneurysm Clips

1. In the event that it is unclear whether a patient does or does not have an aneurysm clip in place, plain films should be obtained. Alternatively, if available, any cranial plain films, CT, or MR examination that may have taken place in the recent past (i.e., subsequent to the suspected surgical date) should be reviewed to assess for a possible intracranial aneurysm clip.
2. In the event that a patient is identified to have an intracranial aneurysm clip in place, the MR examination should not be performed until it can be documented that the type of aneurysm clip within that patient is MR safe or MR conditional. All documentation of types of implanted clips, dates, etc., *must* be in writing and signed by a licensed physician. Phone or verbal histories and histories provided by a nonphysician are not acceptable. Fax copies of operative reports, physician statements, etc. are acceptable as long as a legible physician signature accompanies the requisite documentation. A written history of the clip itself having been appropriately tested for ferromagnetic properties (and description of the testing methodology used) prior to implantation by the operating surgeon is also considered acceptable if the testing follows the deflection test methodology established by ASTM International.
3. All implanted intracranial aneurysm clips that are documented in writing to be composed of titanium (either the commercially pure or the titanium alloy types) can be accepted for scanning without any other testing.
4. All nontitanium intracranial aneurysm clips manufactured in 1995 or later for which the manufacturer's product labeling continues to claim MR compatibility may be accepted for MR scanning without further testing.
5. Clips manufactured prior to 1995 require either pretesting (according to the ASTM deflection test methodology) prior to implantation or individual review of previous MRI of the clip or brain in that particular case, if available. By assessing the size of the artifact associated with the clip relative to the static field strength on which it was studied, the sequence type, and the MRI parameters selected, an opinion may be issued by one of the site's level 2 MR attending radiologists as to whether the clip demonstrates significant ferromagnetic properties or not. Access to the MR scanner would then be based on that opinion.
6. A patient with an aneurysm clip (or other implant) may have safely undergone a prior MR examination at any given static magnetic field strength. This fact in and of itself is not sufficient evidence of the implant's MR safety and should not solely be relied upon to determine the MR safety or compatibility status of that aneurysm clip (or other implant).

   Variations in static magnetic field strength, static magnetic field spatial gradient, orientation of the aneurysm clip (or other implant) to the static magnetic field or static field gradient, rate of motion through the spatial static field gradient, etc., are all variables that are virtually impossible to control or reproduce. These variables may not have resulted in an adverse event in one circumstance but may result in significant injury or death on a subsequent exposure. For example, a patient who went blind from interactions between the metallic foreign body in his retina and the spatial static fields of the MR scanner entered the magnet and underwent the entire MR examination without difficulty; he went blind only on exiting the MR scanner at the completion of the examination.
7. Barring availability of either pretesting or prior MRI data of the clip in question, a risk–benefit assessment and review must be performed in each case individually. Further, for patients with intracranial clips with no available ferromagnetic or imaging data, should the risk–benefit ratio favor the performance of the MR study, the patient or guardian should provide written informed consent that includes death as a potential risk of the MRI procedure before that patient is permitted to undergo an MR examination.

N. Patients in Whom There Are or May Be Cardiac Pacemakers or Implantable Cardioverter Defibrillators

It is recommended that the presence of implanted cardiac pacemakers or implantable cardioverter defibrillators (ICDs) be considered a rel-

ative contraindication for MRI. MRI of patients with pacemakers and ICDs ("device patients") is *not* routine. Should an MRI be considered, it should be done on a case-by-case and site-by-site basis, and only if the site is staffed with individuals with the appropriate radiology and cardiology knowledge and expertise on hand. As of this writing, no cardiac pacing and/or defibrillating devices are labeled safe or conditionally safe for MRI scanning. Pacemaker and/or ICD leads may also present a hazard in the absence of any implant connected to them.

The protective circuitry of pacemakers and ICDs and their resistance to electromagnetic interference (EMI) has steadily improved over the years. Therefore, recently marketed ("modern") devices may be safer in the MRI environment. However, the committee eschews the term "modern" when referring to a particular device, recognizing that all devices currently marketed contain legacy components that may or may not be resistant to the forces and EMI present in the MRI suite. Future devices, unless appropriately tested and labeled as such, should not be regarded as safe for MRI simply because they are "modern" or recently manufactured.

Unexpected programming changes, inhibition of pacemaker output, failure to pace, transient asynchronous pacing, rapid cardiac pacing, the induction of ventricular fibrillation, heating of the tissue adjacent to the pacing or ICD system, early battery depletion, and outright device failure requiring replacement may all occur during MRI of patients with pacemakers or ICDs. The committee notes that multiple deaths have occurred under poorly and incompletely characterized circumstances when device patients underwent MRI. These deaths may have occurred as a result of pacemaker inhibition, failure to capture or device failure (resulting in prolonged asystole), and/or rapid cardiac pacing or asynchronous pacing (resulting in the initiation of ventricular tachycardia or fibrillation).

Ideally, the nonemergent patient should be apprised of the risks associated with the procedure and should provide prospective written informed consent prior to the initiation of MRI. While the majority of reported deliberate scans of device patients have proceeded without mishap when appropriate precautions were taken, there may be underreporting of adverse events, including deaths [58]. Thus, assignment of a risk–benefit ratio to the performance of MRI in a device patient is difficult. While the risk may be low, device patients who are considered for MRI should be advised that life-threatening arrhythmias might occur during MRI and serious device malfunction might occur, requiring replacement of the device.

Should any MRI examination be contemplated for a patient with an implanted pacemaker or ICD, it is recommended that radiology and cardiology personnel and a fully stocked crash cart be readily available throughout the procedure in case a significant arrhythmia develops during the examination that does not terminate with the cessation of the MR study. The cardiologist should be familiar with the patient's arrhythmia history and the implanted device. A programmer that can be used to adjust the device as necessary should be readily available. All such patients should be actively monitored for cardiac and respiratory function throughout the examination. At a minimum, ECG and pulse oximetry should be used. At the conclusion of the examination, the cardiologist should examine the device to confirm that the function is consistent with its preexamination state. Follow-up should include a check of the patient's device at a time remote (1–6 weeks) after the scan to confirm appropriate function.

Should an MRI (or entry into the magnet area) be performed inadvertently on a patient with a pacemaker or ICD, the patient's cardiologist should be contacted before the patient's discharge from the MRI suite. The importance of examination of the device prior to the patient's leaving the MRI suite cannot be overstated.

O. Site Emergency Preparedness

There are many factors to consider when attempting to ensure that an MR imaging facility is adequately and appropriately prepared to handle any of several types of emergencies that might impact MR scanners of varied design types. Appendix 4 addresses these issues in some detail and provides specific guidelines to help anticipate and safeguard sites from some of the more common emergencies and disasters that might affect MR imaging facilities.

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Appendices 1–4 appear on the following pages.

APPENDIX 1: Personnel and Zone Definitions

PERSONNEL DEFINITIONS

Non-MR Personnel

Patients, visitors, or facility staff who do not meet the criteria of level 1 or level 2 MR personnel will be referred to as non-MR personnel. Specifically, non-MR personnel will be the terminology used to refer to any individual or group who has not within the previous 12 months undergone the designated formal training in MR safety issues defined by the MR safety director of that installation.

Level 1 MR Personnel

Individuals who have passed minimal safety educational efforts to ensure their own safety as they work in Zone III will be referred to as level 1 MR personnel (e.g., MRI department office staff and patient aides).

Level 2 MR Personnel

Individuals who have been more extensively trained and educated in the broader aspects of MR safety issues, including issues related to the potential for thermal loading or burns and direct neuromuscular excitation from rapidly changing gradients, will be referred to as level 2 MR personnel (e.g., MRI technologists, radiologists, and radiology department nursing staff).

ZONE DEFINITIONS

Zone I

This region includes all areas that are freely accessible to the general public. This area is typically outside the MR environment itself and is the area through which patients, health care personnel, and other employees of the MR site access the MR environment.

Zone II

This area is the interface between the publicly accessible uncontrolled Zone I and the strictly controlled Zone III (see below). Typically, the patients are greeted in Zone II and are not free to move throughout Zone II at will, but rather are under the supervision of MR personnel. It is in Zone II that the answers to MR screening questions, patient histories, medical insurance questions, etc. are typically obtained.

Zone III

This area is the region in which free access by unscreened non-MR personnel or ferromagnetic objects or equipment can result in serious injury or death as a result of interactions between the individuals or equipment and the particular environment of the MR scanner. These interactions include, but are not limited to, those with the MR scanner's static and time-varying magnetic fields. All access to Zone III is to be strictly restricted, with access to regions within it (including Zone IV, see below) controlled by, and entirely under the supervision of, MR personnel.

Zone IV

This area is synonymous with the MR scanner magnet room itself. Zone IV, by definition, will always be located within Zone III as it is the MR magnet and its associated magnetic field which generates the existence of Zone III.

Non-MR personnel should be accompanied by, or under the immediate supervision of and visual contact with, one specifically identified level 2 MR person for the entirety of their duration within Zone III or Zone IV restricted regions.

Level 1 and 2 MR personnel may move freely about all zones.

APPENDIX 2: MR Facility Safety Design Guidelines

The goal of MR safety is to prevent harm to patients, though an MR facility cannot simply adopt one or two interventions and hope to successfully attain this objective. According to safety and human factors engineering principles, multiple safety strategies must be adopted to be effective. This approach is sometimes termed "defense in depth." The safety strategies outlined in the main body of this Guidance Document for MR Safe Practices include, for instance, policies that restrict personnel access, specialized training and drills for MR personnel, and warning labels for devices to be brought into Zone IV regions.

Along with these people-oriented strategies of policies and training, organizations need also to adopt the strategies of safety-oriented architectural and interior design. These design elements can support the other safety strategies by making them easier or more obvious to follow. The architectural enhancements described herein add one or more strong barriers to enhance "defense in depth."

This appendix includes descriptions of architectural and interior design recommendations organized around the many MR suite functional areas. Note that a facility's design can encourage safety and best practices by improving the flow of patients, various health care personnel, and equipment and devices, and not just by preventing MR unsafe items from becoming missiles, or screening out patients with hazardous implanted devices.

Placing design elements strategically in a suite layout such that the element supports best-practice work flow patterns will increase compliance with safer practices. For example, having a private area for patient screening interviews will make it more likely the patients will disclose sensitive types of implants. Another example of designing for safety is to include dedicated space and temporary storage for MR Unsafe equipment (e.g., ferromagnetic IV poles, transport stretchers) out of direct sight and away from people flow patterns.

Effective and safe MRI suites must balance the technical demands of the MR equipment with local and state building codes, standards of accrediting bodies, clinical and patient population needs, payor requirements, and a collage of civil requirements from the Health Insurance Portability and Accountability Act (HIPAA) to the Americans with Disabilities Act (ADA).

In an effort to better match appropriate facility design guidelines with levels of patient acuity and care, the ACR MR Safety Committee is currently developing level designations for MRI facilities in conjunction with the efforts of committees from other societies and organizations. These will address customization of requirements for sites with varying anticipated patient care sedation, anesthesia, and/or interventional activities.

While it would be desirable to provide a universal MRI suite safety design, the variables are too numerous to adequately address in a single template. The following MRI Facility Safety Design Guidelines provide information in support of planning, design, and construction of MR facilities, including updates to existing MR facilities, which enhance the safety of patients, visitors, and staff. This information is intended to supplement and expand upon patient safety guidance provided throughout the ACR Guidance Document for MR Safe Practices.

1. MR Equipment Vendor Templates

Design templates provided by MR equipment manufacturers are invaluable in developing suites that meet the minimum technical siting requirements for the specific equipment. Vendor design templates, however, typically depict only the control and equipment rooms, in addition to the magnet room, Zone IV.

Patient/family waiting, interview areas, physical screening/changing areas, access controls, storage, crash carts, induction, medical gas services, holding areas for patients after screening, infection control provisions, and interventional applications, among many other issues, are not addressed in typical vendor-provided drawings. These issues are left to facility owners, operators, and their design professionals to resolve. The guidance which follows is designed to address many of these issues which directly impact safety within the MR suite.

2. Patient Interview/Clinical Screening Areas (Zone II)

Reviewing the patient Safety Screening Form and the MR Hazard Checklist requires discussing confidential personal information. To facilitate full and complete patient disclosure of their medical history, this clinical screening should be conducted in an area which provides auditory and visual privacy for the patient. Facilities should prospectively plan for electronic patient medical records, which are useful in clinical screening, and should provide access to records in the MR suite in support of clinical patient screening.

Clinical screening of inpatients may be completed in the patient room for hospital-based MR facilities. However, all screenings are to be double-checked and verified by appropriately trained MR personnel before MR examination.

3. Physical Screening and Patient Changing/Gowning Rooms (Zone II)

All persons and objects entering Zone III should be physically screened for the presence of ferromagnetic materials which, irrespective of size, can become threats in proximity to the MR scanner. A location should be provided for patients in which they may change out of their street clothes and into a facility-provided gown or scrubs, if or as deemed appropriate. For those facilities that either do not provide space for, or do not require, patient changing, the facility must provide alternative means of identifying and removing items that the patient may have brought with them that might pose threats in the MR environment.

A high-strength handheld magnet is a recommended tool to evaluate the gross magnetic characteristics of objects of unknown composition. Magnetic strength for these permanent magnets falls off quickly as one moves away from the face of the magnet. Thus, these may not demonstrate attraction for ferromagnetic components which are not superficially located or cannot for whatever reason be brought into close proximity with the surface of this handheld magnet.

Ferromagnetic detection systems have been demonstrated to be highly effective as a quality assurance tool, verifying the successful screening and identifying ferromagnetic objects which were not discovered by conventional screening methods. It is recommended that new facility construction anticipate the use of ferromagnetic detection screening in Zone II and provide for installation of the devices in a location which facilitates use and throughput. Many current ferromagnetic detection devices are capable of being positioned within Zone III, even at the door to the magnet room; however, the recommended use of ferromagnetic detection is to verify the screening of patients before they pass through the controlled point of access into Zone III.

Physical screening of patients should consist of removal of all jewelry, metallic or ferromagnetic objects, onplants, and prostheses (as indicated by manufacturer's conditional use requirements and physician instructions) and either having patients change out of their street clothes into facility-provided gowns or scrubs or thorough screening of street clothes, including identifying the contents of pockets and the composition of metallic fibers, fasteners, and reinforcing.

4. Transfer Area and Ferrous Quarantine Storage (Zone II)

Patients arriving with wheelchairs, walkers, portable oxygen, and other appliances that may be unsafe in the MR environment should be provided by the facility with appropriate MR safe or MR conditional appliances. An area should be provided to transfer the patient from unsafe appliances to ones appropriate to the MR environment. Unsafe appliances brought by the patient should be secured in a "ferrous quarantine" storage area, distinct from storage areas for MR safe and MR conditional equipment, and ideally locked out of sight. Patient belongings should be retrieved from the ferrous quarantine only when discharging the patient to whom the objects belong.

5. Access Control (Zone III and Zone IV)

Means of physically securing and restricting access to Zone III from all adjacent areas must be provided. Independent access into Zone III must be limited to only appropriately trained MR personnel.

6. Patient Holding (Zone III)

Depending upon facility capacity and patient volume, it may be advisable to provide a postscreening patient holding area. Zone III holding areas should be equipped and appointed to prevent patient exit and subsequent reentry. This will help prevent the inadvertent—or even intentional—introduction of unscreened objects and personnel.

Many multitechnique radiology facilities combine patient holding and/or induction areas for patients undergoing different types of imaging examinations. This presents safety challenges when, for example, patients scheduled to undergo CT are held in a patient holding area shared by postscreening MR patients. As CT patients would not typically be screened for MR contraindications or ferrous materials, this poses risks to both the CT patient with a contraindicated implant and to those in the MRI Zone IV should an unscreened individual inadvertently enter with a ferrous object or implant.

Unless all persons in patient holding areas used for postscreening MR patients are screened for MRI, the practice of shared patient holding areas

between MR and other techniques is discouraged. Ultimately it is the responsibility of trained MR staff to verify the screening of any commingled patient prior to permitting them to enter Zone III and Zone IV.

In all MR facilities, Zone III is required to be secured and access limited to only MR personnel and successfully MR prescreened non-MR personnel accompanied by MR personnel. Ideally, facilities should be designed so that patients undergoing other techniques are not commingled with postscreening MR patients.

7. Lines of Sight and Situational Awareness (Zone III)

Trained MR personnel are arguably the single greatest safety resource of MR facilities. These individuals should be afforded visual control over all persons entering or exiting Zone III or Zone IV. The technologist seated at the MR operator console should therefore be able to view not only the patient in the MR scanner but also the approach and entrance into Zone IV. When practical, suites should also be prospectively designed to provide a view from the MR operator's console to patient holding areas. If this cannot be satisfactorily achieved by direct line of sight, remote video viewing devices are an acceptable substitute toward accomplishing this objective.

The technologist at the console should also be provided with a view to induction and recovery areas within the MR suite, as applicable.

8. Emergency Resuscitation Equipment (Zone II or Zone III)

Because of risks associated with contrast agents, sedation, anesthesia, and even the frail health of patients undergoing MR examinations, it is advised that each facility have appropriate provisions for stabilization and resuscitation of patients.

It is recommended that crash carts and emergency resuscitation equipment be stored in a readily accessible area in either Zone II or Zone III. This emergency resuscitation equipment is to be appropriately labeled and also tested and verified as safe for usage in MR environment for the anticipated conditions of usage.

MR facilities should maintain a supply of emergency medications to treat adverse reactions to administered contrast agents.

MR facilities providing care to patients who require clinical support during the MR examination should have emergency response equipment and personnel, trained in MR safety issues as well as trained to respond to anticipatable adverse events, readily available to respond to patient adverse events or distress in the MR arena.

9. Fringe Magnetic Field Hazards (Zone III)

For many MR system installations, magnetic fringe fields which project beyond the confines of the magnet room superimpose potential hazards on spaces which may be outside the MR suite, potentially on levels above or below the MR site and perhaps even outside the building. Facilities must identify all occupyable areas, including those outside the MR suite (including rooftops, storage areas, mechanical closets, etc.) which are exposed to potentially hazardous magnetic fringe field strengths. Areas of potential hazard must be clearly identified, and access to these areas must be restricted, just as they would be within the MR suite.

10. Cryogen Safety (Zone IV)

Liquid helium and liquid nitrogen represent the most commonly used cryogens in MR environments. The physical properties of these cryogenic liquids present significant potential safety hazards. If exposed to room air, these cryogenic liquids will rapidly boil off and expand into a gaseous state. This produces several potential safety concerns, including:

- Asphyxiation is a possibility as cryogenic gases replace oxygenated air.
- Frostbite may occur at the exceedingly low temperatures of these cryogenic liquids.
- Fire hazards can exist in the unlikely event of a quench, especially if some of the cryogenic gases escape into the magnet room/Zone IV.
- Hyperbaric pressure considerations within Zone IV can rarely exist in the unlikely event of a quench in which some of the cryogenic gases escape into the magnet room/Zone IV.

a. Cryogen Fills

Though contemporary superconducting magnets require cryogen refills only infrequently, there is still almost always the need to periodically bring hundreds of liters of liquid cryogen to the magnet. It is because of the risks to persons near the magnet and storage/transport dewars that transfill operations should be undertaken with great care and only by appropriately trained personnel.

- Dewars containing cryogenic liquids should never be stored inside an MRI facility or indeed any enclosed facility unless in a facility specifically designed to manage the associated pressure, temperature, and asphyxiation risks.
- A cryogen transfill should never be attempted by untrained personnel or even with any unnecessary personnel in attendance, including MR personnel staff and patients, within Zone IV.
- Cryogen transfills should only be performed with appropriate precautions in place to prevent pressure entrapment and asphyxiation.

b. Magnet Room Cryogen Safety

For most MRI systems, if the magnet quenches, the escaping cryogenic gases are ducted outside the building to an unoccupied discharge area. However, there have been documented failures of cryogen vent/quench pipe assemblies which have led to considerable quantities of cryogenic gases being inadvertently discharged into the magnet room/Zone IV. The thermal expansion of the cryogens, if released into the magnet room, can positively pressurize the magnet room and entrap persons inside until such time as the pressure is equalized.

The following recommended MRI suite design and construction elements reduce patient and staff risks in the unlikely event of a quench in which the cryogen vent pathway (quench pipe) ruptures or leaks into Zone IV:

- All magnet rooms/Zone IV regions for superconducting magnets should be provided with an emergency exhaust pathway. The emergency exhaust grille is to be located in the ceiling opposite the entrance to the magnet room (Zone IV) door. At this location, when activated in the unlikely event of a quench breach, the exhaust fan is positioned to draw the vaporous cloud of cryogenic gas away from the door providing exit from the magnet room.
- Many MR manufacturers are now requiring that magnet rooms for superconducting magnets also be provided with an additional form of passive pressure relief/pressure equalization to minimize the risks of positive-pressure entrapment. Designs for passive pressure relief mechanisms should follow design criteria similar to those of cryogen vent pathway and active exhaust, including discharge to a protected area, as described in section 10.c below.

Some MR facilities are constructed without open waveguides or glass observation windows to Zone IV regions. In these facilities, the potential risks of entrapment are even greater and may warrant an additional degree of attention in this regard.

While it can provide a degree of redundancy, it should be noted that, even with an exhaust fan, designing the door to Zone IV to swing out-

ward is not, by itself, an appropriate means of pressure relief. In a severe positive-pressure situation, unlatching an outward-swinging door might permit the door to burst open with tremendous pressure, potentially injuring person(s) opening the door. If employed as the only means of pressure equalization, an outward-swinging door may actually introduce new hazards to any staff person attempting to open the door to a pressurized magnet room from the outside.

Similarly, though it has proven effective in life-threatening situations, breaking a control window should not be advocated as a primary means of relieving/equalizing Zone IV pressure in a quench situation. It should be noted that the current construction of many RF-shielded observation windows is such that breaking the window would be very difficult, further diminishing that as a viable means of pressure relief.

Once provided with appropriate pressure equalization and emergency exhaust, magnet room door swing direction and design should be left to the discretion of a facility and their design professionals.

c. Cryogen Vent Pathway

Obstructions, inappropriate pipe materials, insufficient pipe caliber and/or length, or faulty connections in the length of the cryogen vent pathway can cause failure between the magnet and the point of discharge. An evaluation of the current cryogen vent piping/ducting assembly is recommended to help identify and correct potential weaknesses that could potentially fail in a quench. Facilities are advised to evaluate the design and inspect the construction of their cryogen vent system.

Because minimum design requirements for some cryogen vent systems have been revised by magnet system vendors, facilities should obtain current standards from the original equipment manufacturers to use in evaluating their cryogen vent assembly and not rely on original siting requirements.

Beyond the assessment of the current construction of the cryogen vent system, it is prudent for MRI facilities:

- To inspect cryogen vent systems at least annually, identifying stress or wear of pipe sections and couplings, loose fittings and supports, or signs of condensation or water within the cryogen vent pathway, which may indicate a blockage.
- Following any quench of a superconducting magnet, to conduct a thorough inspection of the cryogen vent system, including pipe sections, fittings, couplings, hangers, and clamps, prior to returning the magnet to service.

Because obstructions or occlusions of the cryogen vent can increase the likelihood of rupture in a quench event, facilities should ensure that:

- The discharge point has an appropriate weatherhead that prevents horizontal, wind-driven precipitation from entering, collecting, or freezing in the quench exhaust pipe.
- The discharge point is high enough off the roof or ground surface that snow or debris cannot enter or occlude the pipe.
- The discharge is covered by a material having sufficiently small openings to prevent birds or other animals from entering the quench pipe, while not occluding cryogenic gaseous egress in a quench situation.

Facilities that discover failings in any of these basic protections of the cryogen discharge point should immediately take additional steps to verify the patency of the cryogen vent and provide the minimum current discharge protections recommended by the original equipment manufacturer.

To protect persons from cryogen exposure at the point of discharge:

- At the point of cryogen discharge, a quench safety exclusion zone with a minimum clear radius of 25 ft (8 m) should be established and clearly marked with surface warnings and signage.
- The quench safety exclusion zone should be devoid of serviceable equipment, air intakes, operable windows, or unsecured doors that either require servicing or offer a pathway for cryogenic gasses to reenter the building.
- Persons who must enter this quench safety exclusion zone, including incidental maintenance personnel and contractors, should be permitted to do so only after receiving specific instruction on quench risks and response.

11. MR Conditional Devices (Zone IV)

The normal or safe operation of many medical devices designed for use in the MR environment may be disrupted by exposure to conditions exceeding the device's conditional rating threshold. It is advisable for MR facilities to identify the maximum conditional rating for static field and spatial gradient exposure for each MR Conditional device that may be brought into Zone IV. For prospective installations, it is recommended that the location of critical isogauss line(s) be identified for MR Conditional equipment and devices used within the MR suite and delineated on the floor and walls of the magnet room to aid in the positioning and safe and effective operation of said equipment.

All MR facilities should evaluate all MR Conditional patient monitoring, ventilators, medication pumps, anesthesia machines, monitoring devices, biopsy, and other devices and equipment which may be brought into the magnet room for magnetic field tolerances. Facilities should consider providing physical indications of critical gauss lines in the construction of the magnet room to promote the safe and effective use of MR Conditional equipment, as appropriate.

12. Infection Control (Zone IV)

Because of safety concerns regarding incidental personnel within the MR suite, restricting housekeeping and cleaning personnel from Zone III and/or Zone IV regions may give rise to concerns about the cleanliness of the MR suite. Magnet room finishes and construction details should be designed to facilitate cleaning by appropriately trained staff with nonmotorized equipment. Additionally, as the numbers of MR-guided procedures and interventional applications grow, basic infection control protocols, such as seamless floorings, scrubbable surfaces, and hand-washing stations, should be considered.

13. Limits of Applicability and Recommended Design Assistance

The facility design issues identified in this document address only general safety design issues for MRI suites. There are a multitude of site-specific and magnet-specific operational and technical design considerations relevant to MR facility design and construction that are not addressed in these guidelines. These issues include, but are not limited to, patient acuity, staff access, technique conflicts, vibration sensitivity, throughput and efficiency, HIPAA considerations, magnetic contamination, sound transmission, magnet shim tolerances, shielding design, moving metal interferences, MR equipment upgrades, electromagnetic interference, and many others.

In addition to incorporating the guidance from this document, a facility would be well advised to seek expert assistance in the planning and design of MRI and multitechnique radiology suites.

APPENDIX 3: Safety Screening Form, MR Hazard Checklist, and Patient Instructions

SAFETY SCREENING FORM FOR MAGNETIC RESONANCE (MR) PROCEDURES

Date_____
Name (first middle last)_____
Female [ ] Male [ ] Age_____ Date of Birth_____
Height_____ Weight_____
Why are you having this examination (medical problem)?
_____

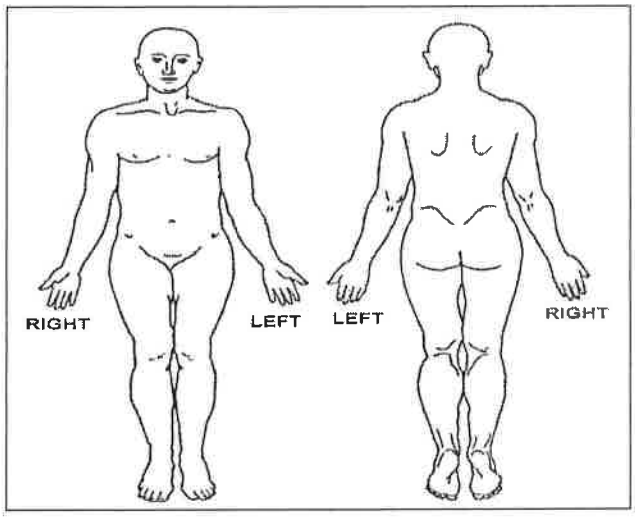
YES NO
Have you ever had an MRI examination before and had a problem?
____ ____
If yes, please describe_____
Have you ever had a surgical operation or procedure of any kind?
____ ____
If yes, list all prior surgeries and approximate dates:
_____
_____
Have you ever been injured by a metal object or foreign body (e.g., bullet, BB, shrapnel)?
____ ____
If yes, please describe_____
_____

Have you ever had an injury from a metal object in your eye (metal slivers, metal shavings, other metal object)?
____ ____
If yes, did you seek medical attention?_____
If yes, describe what was found_____
Do you have a history of kidney disease, asthma, or other allergic respiratory disease?
____ ____
Do you have any drug allergies?
____ ____
If yes, please list drugs_____
_____
Have you ever received a contrast agent or X-ray dye used for MRI, CT, or other X-ray or study?
____ ____
Have you ever had an X-ray dye or magnetic resonance imaging (MRI) contrast agent allergic reaction?
____ ____
If yes, please describe_____
_____
Are you pregnant or suspect you may be pregnant?
____ ____
Are you breast feeding?
____ ____
Date of last menstrual period_____ Post-menopausal?_____

MR Hazard Checklist

Please mark on the drawing indicating the location of any metal inside your body or site of surgical operation.

The following items may be harmful to you during your MR scan or may interfere with the MR examination. You must provide a "yes" or "no" for every item. Please indicate if you have or have had any of the following:



YES NO
____ ____ Any type of electronic, mechanical, or magnetic implant
Type_____
____ ____Cardiac pacemaker
____ ____Aneurysm clip
____ ____Implantable cardiac defibrillator
____ ____Neurostimulator
____ ____Biostimulator
Type_____
____ ____Any type of internal electrodes or wires
____ ____Cochlear implant
____ ____Hearing aid
____ ____Implanted drug pump (e.g., insulin, baclofen, chemotherapy, pain medicine)
____ ____Halo vest
____ ____Spinal fixation device
____ ____Spinal fusion procedure
____ ____Any type of coil, filter, or stent
Type_____
____ ____Any type of metal object (e.g., shrapnel, bullet, BB)
____ ____Artificial heart valve
____ ____Any type of ear implant
____ ____Penile implant
____ ____Artificial eye
____ ____Eyelid spring

Safe MR Practices

____ ____Any type of implant held in place by a magnet
Type_____
____ ____Any type of surgical clip or staple
____ ____Any IV access port (e.g., Broviac, Port-a-Cath, Hickman, PICC line)
____ ____Medication patch (e.g., nitroglycerine, nicotine)
____ ____Shunt
____ ____Artificial limb or joint
What and where_____
____ ____Tissue expander (e.g., breast)
____ ____Removable dentures, false teeth, or partial plate
____ ____ Diaphragm, IUD, pessary
Type_____

____ ____Surgical mesh
Location_____
____ ____Body piercing
Location_____
____ ____Wig, hair implants
____ ____Tattoos or tattooed eyeliner
____ ____Radiation seeds (e.g., cancer treatment)
____ ____Any implanted items (e.g., pins, rods, screws, nails, plates, wires)
____ ____Any hair accessories (e.g., bobby pins, barrettes, clips)
____ ____Jewelry
____ ____Any other type of implanted item
Type_____

Instructions for the Patient

1. You are urged to use the ear plugs or headphones that we supply for use during your MRI examination since some patients may find the noise levels unacceptable, and the noise levels may affect your hearing.
2. Remove all jewelry (e.g., necklaces, pins, rings).
3. Remove all hair pins, bobby pins, barrettes, clips, etc.
4. Remove all dentures, false teeth, partial dental plates.
5. Remove hearing aids.
6. Remove eyeglasses.
7. Remove your watch, pager, cell phone, credit and bank cards, and all other cards with a magnetic strip.
8. Remove body piercing objects.
9. Use gown, if provided, or remove all clothing with metal fasteners, zippers, etc.

I attest that the above information is correct to the best of my knowledge. I have read and understand the entire contents of this form, and I have had the opportunity to ask questions regarding the information on this form.

Patient signature_____
MD/RN/RT signature_____
Date_____
Print name of MD, RN, RT_____

For MRI Office Use Only

Patient Name_____
Patient ID Number_____
Referring Physician_____

Procedure_____
Diagnosis_____
Clinical History_____

Hazard Checklist for MRI Personnel

YES NO
____ ____Endotracheal tube
____ ____Swan-Ganz catheter
____ ____Extraventricular device
____ ____Arterial line transducer

YES NO
____ ____Foley catheter with temperature sensor and/or metal clamp
____ ____Rectal probe
____ ____Esophageal probe
____ ____Tracheotomy tube
____ ____Guidewires

APPENDIX 4: MR Facility Emergency Preparedness Guidelines

Health care facilities have a unique obligation to minimize the disruption from disasters and hasten their ability to restore critical patient care services when interrupted.

Those charged with the operation of MRI facilities have the added complexities of protecting not only the staff and structure, but also the equipment, which may be extraordinarily sensitive to changes in its environment, including vibration, power supply, and water damage.

In the fall of 2005, many watched as Hurricanes Katrina and Rita devastated vast swathes of the U.S. Gulf Coast. Those facilities which were well prepared for the damage, loss of power, and other failures of infrastructure fared far better than those that that were not.

Even those not in the likely path of future Gulf hurricanes may have to contend with earthquakes, tornadoes, fires, ice storms, snowstorms, or blackouts, at some point. Particularly those involved in providing patient care should look to how we will provide care at the times when it is most widely and desperately needed. We may find that, while individuals are willing, the facilities, equipment, and infrastructure required to provide clinical care have not been adequately protected.

1. Water Damage

Whether from roof failure, burst pipes, storm surge, or rising rivers, every facility has the potential for water damage to equipment and facilities. Damage can range from inconveniences cured by a couple of hours with a wet–dry vacuum to flooding of equipment electronics. It takes only a small quantity of water in contact with an MRI scanner to incapacitate or destroy the equipment.

To keep leaking roofs, burst pipes, or other overhead damage from dousing MRI equipment, it is recommended that facilities prepare by covering gantries and equipment with sturdy plastic, taped in place, when water damage is an anticipated possibility. To keep processors and gradient cabinets from becoming swamped in a flood situation, electronics that can be lifted off the ground should be moved as far off the floor as possible. RF shields, particularly the floor assembly, may be significantly damaged and need to be replaced in a flood situation if they are not designed to be protected against water damage.

During the 2005 hurricanes, many hospitals and imaging facilities that had emergency generators to help restore power discovered that their sites had generators, or other critical supplies, in basements or other low-lying areas that were flooded. Facilities should evaluate risks from water damage and assess their preparations for failure of the building enclosure as well as the potential for a flood situation.

2. Structural Damage

MRI presents a particular challenge with structural failure. Although unlikely with current magnet systems, vibrations from seismic events do have the potential to initiate a quench of the magnet system. Structural damage or motion may also damage the RF shield enclosure, potentially degrading image quality until the shield is repaired.

3. Power Outage

Without electrical power to the vacuum pump/cold head to keep the cryogen within a superconducting MRI magnet liquefied, the cryogen will begin to boil off at an accelerated rate. Depending upon cryogen vent design and boil-off rate, the additional cryogenic gas discharge may freeze any accumulated water in the cryogen vent, occluding the pipe and increasing the possibility for a cryogen vent breach in the event of a quench.

At some point, if power to the vacuum pump is not restored, likely a couple days to perhaps a week after power is lost, the magnet will spontaneously quench, discharging most or all of its remaining cryogenic gasses. This poses a safety risk to anyone near the discharge and runs a small but finite risk of potentially permanently damaging the magnet coils.

However, if power to the vacuum pump/cold head and cryogen levels is restored prior to a quench, there should be no long-term consequences to the magnet's operation from a power interruption.

Temporary electrical power may be provided either through on-site or portable generators. Cogeneration, or generating one's own electricity all the time, may not be economically feasible for smaller or standalone sites but is increasingly appealing to hospitals for a number of reasons, with emergency capacity being only one.

4. Quench

During the 2005 hurricanes, facilities, fearing extensive damage to their MRI systems from water or protracted power outages, manually initiated preemptive quenches. Under the best circumstances, a quench subjects a magnet to a change of 500°F (260°C) thermal shock within a few dozen seconds, which can cause major physical damage. Rarely, it is possible for the venting cryogenic gases to breach the quench tube and cause significant damage to the magnet room and/or jeopardize the safety of those in the vicinity. At one New Orleans area facility that elected to preemptively quench its magnets, the quench tube reportedly failed and the pressure from the expanding cryogen blew out the control room radiofrequency window (personal communication, Tobias Gilk, October 2005).

Because of the risks to personnel, equipment, and physical facilities, manual magnet quenches are to be initiated only after careful consideration and preparation. In addition to following those specific recommendations provided by the MRI manufacturer, a facility should initiate a preemptive quench in nonemergent situations only after verifying the function of emergency exhaust systems, verifying or providing means of pressure relief, and performing a preliminary visual inspection of the cryogen vent pipe as it leaves the MR unit to check for signs of water or ice inside the pipe (including water leaking from fittings or condensation forming on vent pipe sections).

5. Fire and Police

Though very infrequent, MR suites have been the scene of emergencies requiring fire and/or police response. While it is quite likely this will be the first time many of the responders have been to an MR suite, this should not be the first time that responding organizations have been introduced to the safety issues for MR. Sites are encouraged to invite police and fire representatives to presentations on MR safety and to provide them with facility tours.

6. Code

In the event that a person within the MR suite should require emergency medical attention, it is imperative that those responding to a call for assistance are aware of, and comply with, MR safety protocols. This includes nurses, physicians, respiratory technicians, paramedics, security personnel, and others.

The impulse to respond immediately must be tempered by an orderly and efficient process to minimize risks to patients, staff, and equipment. This requires specialized training for code teams and, as with fire and police responses, clear lines of authority for screening, access restrictions,

and quench authority. Full resuscitation of patients within Zone IV is complicated by the inability to accurately interpret electrocardiographic data. Furthermore, this may place all within Zone IV at risk of injury from ferromagnetic objects which may be on, within, or brought into Zone IV by emergency response personnel responding to a code if one is called in that area. Therefore, after basic cardiopulmonary resuscitation (airway, breathing, chest compressions) is initiated, the patient should be immediately moved out of Zone IV to a prospectively designated location where the code can be run or where the patient will remain until the arrival of emergent response personnel.

It is strongly advised that all MR facilities perform regular drills to rehearse and refine emergency response protocols to protect patients, MR staff, and responders.

7. Prevention

While it is the nature of emergencies to be surprises, we can anticipate the types of incidents that have higher likelihoods given our facilities, practices, and locations. Every facility can anticipate the potential for flooding, fire, and code situations. In addition to these, many areas (e.g., California and coastal Alaska) can expect earthquakes. The central and southern plains states of the United States can anticipate tornados. Colder climates can expect massive snows or ice storms.

State and federal offices of emergency preparedness are dedicated to anticipating and preparing for the specific threats to your region. These offices can serve as an excellent resource regarding risks and strategies for preparation.

Once a disaster has struck, it is important to assess the immediate needs of the community and to restore those critical patient care services first.

Damage to MRI equipment and facilities may not be repaired as quickly. For gravely incapacitated facilities, semitrailer-based MRI units may be the only means of quickly restoring radiology capacity.

All health care facilities should have emergency preparedness plans. The health care plans for MRI facilities should specifically address the unique aspects of MRI equipment. These plans should define who has the authority to authorize nonemergent quenches, procedures for emergency or backup power for the vacuum pump/cold head, as well as instructions on how to protect gantries and sensitive electronics. Facilities should have the necessary supplies pre-positioned and checklists for preparatory and responsive actions. Emergency preparedness plans should also include information necessary for restoring clinical services, including contacts for MRI system vendor, RF shield vendor, cryogen contractor, MR suite architect and construction contractor, local and state officials, and affiliated hospital and professional organizations.

Below are a few questions that may facilitate the development of an emergency preparedness plan specific to the needs of a facility.

- What are the likely/possible natural disasters to affect the area?
- What are the likely/possible man-made disasters to affect the area?
- Is electrical power likely to be interrupted?
- Would other utilities (natural gas, telecommunications, etc.) likely be interrupted?
- What equipment would be inoperative during the emergency?
- What equipment could be damaged by the emergency?
- What equipment should be provided with critical or backup power?
- If the utility service is not quickly restored, what other risks may arise?
- Would patients and staff be able to get to the facility?
- Would patients or staff be trapped at the facility?
- How critical is each patient care service provided at the facility?
- How does the facility protect the equipment needed to support each service?
- If the facility does not have the resources on site, who can provide them?

Attachment C.1.a.MRI Standards and Criteria 7.d.

Revised 2011 (Resolution 19)*

ACR PRACTICE GUIDELINE FOR PERFORMING AND INTERPRETING MAGNETIC RESONANCE IMAGING (MRI)

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

Magnetic resonance imaging (MRI) is a multiplanar imaging method based on an interaction between radiofrequency (RF) electromagnetic fields and certain nuclei in the body (usually hydrogen nuclei) after the body has been placed in a strong magnetic field.[1] MRI differentiates between normal and abnormal tissues, providing a sensitive examination to detect disease. This sensitivity is based on the high degree of inherent contrast due to variations in the magnetic relaxation properties of different tissues, both normal and diseased, and the dependence of the MRI signal on these tissue properties.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

A physician must be responsible for all aspects of the study including, but not limited to, reviewing indications for the examination, specifying the pulse sequences to be performed, specifying the use and dosage of contrast agents, interpreting images, generating official

[1] See ACR Glossary of MR Terms, 5th edition, 2005.

interpretations (final reports), and assuring the quality of the images and the interpretations.

Physicians assuming these responsibilities for MR imaging of all anatomical areas (exclusive of cardiac MRI) should meet one of the following criteria:

Certification in Radiology or Diagnostic Radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or the Collège des Médecins du Québec, and involvement with the supervision, interpretation, and reporting of 300 MRI examinations within the last 36 months.[2]

or

Completion of a diagnostic radiology residency program approved by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada (RCPSC), the Collège des Médecins du Québec, or the American Osteopathic Association (AOA) to include involvement with the supervision, interpretation, and reporting of 500 MRI examinations in the past 36 months.

or

Physicians not board certified in radiology or not trained in a diagnostic radiology residency program who assumes these responsibilities for MR imaging exclusively in a specific anatomical area, excluding cardiac MRI, should meet the following criteria:

Completion of an ACGME approved residency program in the specialty practiced, plus 200 hours of Category I CME in MRI to include, but not limited to: MRI physics, recognition of MRI artifacts, safety, instrumentation, and clinical applications of MRI in the subspecialty area where MRI reading occurs; and supervision, interpretation, and reporting of 500 MRI cases in that specialty area in the past 36 months in a supervised situation. For neurologic MRI, at least 50 of the 500 cases must have been MR angiography (MRA) of the central nervous system.

Specific qualifications for physicians performing cardiac MRI are described in the ACR–NASCI–SPR Practice Guideline for the Performance and Interpretation of Cardiac MRI.

Maintenance of Competence

All physicians performing MRI examinations should demonstrate evidence of continuing competence in the interpretation and reporting of those examinations. If competence is assured primarily on the basis of continuing experience, a minimum of 100 examinations per year is recommended in order to maintain the physician's skills. Because a physician's practice or location may preclude this method, continued competency can also be assured through monitoring and evaluation that indicates acceptable technical success, accuracy of interpretation, and appropriateness of evaluation.

Continuing Medical Education

The physician's continuing education should be in accordance with the ACR Practice Guideline for Continuing Medical Education (CME) and should include CME in MRI as is appropriate to the physician's practice needs.

B. Medical Physicist / MR Scientist

The personnel qualified to carry out acceptance testing and monitoring of MRI equipment for the purposes of this guideline include a medical physicist or an MR scientist.

A Qualified Medical Physicist is an individual who is competent to practice independently one or more subfields in medical physics. The American College of Radiology (ACR) considers certification, continuing education, and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice in one or more subfields in medical physics, and to be a Qualified Medical Physicist. The ACR strongly recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physics in Medicine, or by the American Board of Medical Physics (ABMP).

The appropriate subfield of medical physics for this guideline is Diagnostic Medical Physics. (Previous medical physics certification categories including Radiological Physics, Diagnostic Radiological Physics, and Diagnostic Imaging Physics are also acceptable.)

The Qualified Medical Physicist should meet the ACR Practice Guideline for Continuing Medical Education (CME). (ACR Resolution 17, 1996 – revised in 2012, Resolution 42)

A Qualified MR Scientist is an individual who has a graduate degree in a physical science involving nuclear magnetic resonance (NMR) or MRI. These individuals should have 3 years of documented experience in a clinical MR environment.

The medical physicist/MR scientist must be familiar with the principles of MRI safety for patients, personnel, and the public; the Food and Drug Administration's guidance for MR diagnostic devices; and other regulations pertaining to the performance of the equipment being monitored. The medical physicist/MR scientist must be

[2]Board certification and completion of an accredited radiology residency in the past 24 months will be presumed to be satisfactory experience for the reporting and interpreting requirement.

knowledgeable in the field of nuclear MR physics and familiar with MRI technology, including function, clinical uses, and performance specifications of MRI equipment, as well as calibration processes and limitations of the performance testing hardware, procedures, and algorithms. The medical physicist/MR scientist must have a working understanding of clinical imaging protocols and methods of their optimization. This proficiency must be maintained by participation in continuing education programs of sufficient frequency to ensure familiarity with current concepts, equipment, and procedures.

The medical physicist/MR scientist may be assisted in obtaining test data for performance monitoring by other properly trained individuals. These individuals must be properly trained and approved by the medical physicist/MR scientist in the techniques of performing the tests, the function and limitations of the imaging equipment and test instruments, the reason for the tests, and the importance of the test results. The medical physicist/MR scientist must review and approve all measurements. The MR scientist should meet the ACR Practice Guideline for Continuing Medical Education (CME).

C. Registered Radiologist Assistant

A registered radiologist assistant is an advanced level radiographer who is certified and registered as a radiologist assistant by the American Registry of Radiologic Technologists (ARRT) after having successfully completed an advanced academic program encompassing an ACR/ASRT (American Society of Radiologic Technologists) radiologist assistant curriculum and a radiologist-directed clinical preceptorship. Under radiologist supervision, the radiologist assistant may perform patient assessment, patient management, and selected examinations as delineated in the Joint Policy Statement of the ACR and the ASRT titled "Radiologist Assistant: Roles and Responsibilities" and as allowed by state law. The radiologist assistant transmits to the supervising radiologists those observations that have a bearing on diagnosis. Performance of diagnostic interpretations remains outside the scope of practice of the radiologist assistant. (ACR Resolution 34, adopted in 2006) [1]

D. Radiology Technologist

The technologist should participate in assuring patient comfort and safety, preparing and positioning the patient for the MRI examination, and obtaining the MRI data in a manner suitable for interpretation by the physician. The technologist should also perform frequent quality control testing in accordance with the MRI manufacturer's recommendations.

The technologist performing MRI should:

1. Be certified by the American Registry of Radiologic Technologists (ARRT), the American Registry of MRI Technologists (ARMRIT), or the Canadian Association of Medical Radiation Technologists (CAMRT) as an MRI technologist (RTMR).

   or

2. Be certified by the ARRT and/or have appropriate state licensure and have 6 months supervised clinical experience in MRI scanning.

   or

3. Have an associate's degree in an allied health field or a bachelor's degree and certification in another clinical imaging field and have 6 months of supervised clinical MRI scanning.

To assure competence, the responsible physician should evaluate any technologist who began performing MRI prior to October 1996 and who does not meet the above criteria.

Any technologist practicing MRI scanning should be licensed in the jurisdiction in which he/she practices, if state licensure exists. To assure competence, all technologists must be evaluated by the supervising physician.

III. TECHNIQUES AND INDICATIONS

The currently accepted techniques and indications for MRI are discussed in various ACR Practice Guidelines that are based on anatomic sites of examination. It is important that each site offering MRI have documented procedures and technical expertise and appropriate equipment to examine each anatomic site. Because the clinical applications of MRI continue to expand, the enumerated techniques and indications in the reference documents may not be all-inclusive.

Each site's procedures should be reviewed and updated at appropriate intervals. The final judgment regarding appropriateness of a given examination for a particular patient is the responsibility of the ordering physician or other appropriately licensed health care provider and radiologist. The decision to use MRI to scan a particular part of the human body depends on the MRI software and hardware available and the relative cost, efficacy, and availability of alternative imaging methods. The examination should provide images with suitable contrast characteristics, spatial resolution, signal-to-noise ratio, and section geometry appropriate to the specific clinical indications.

IV. POSSIBLE CONTRAINDICATIONS

Possible contraindications include, but are not limited to, the presence of cardiac pacemakers, ferromagnetic intracranial aneurysm clips, certain neurostimulators, certain cochlear implants, and certain other ferromagnetic foreign bodies or electronic devices [2-5]. Possible contraindications should be listed on a screening questionnaire. All patients should be screened for possible contraindications prior to MRI scanning [6-7]. Published test results and/or on-site testing of an identical device or foreign body may be helpful to determine whether a patient with a particular medical device or foreign body may be safely scanned. There is no known adverse effect of MRI on the fetus. The decision to scan during pregnancy should be made on an individual basis [8].

V. SPECIFICATIONS OF THE EXAMINATION

The examination should be performed within parameters currently approved by the FDA. Examinations that use techniques not approved by the FDA may be considered when they are judged to be medically appropriate.

The written or electronic request for an MRI examination should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation of the examination.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). Additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient's clinical problem or question and consistent with the state's scope of practice requirements. (ACR Resolution 35, adopted in 2006)

Images should be labeled with the following: a) patient identification, b) facility identification, c) examination date, and d) image orientation indicated by unambiguous polarity symbols (e.g., R, L, A, P, H, F).

VI. DOCUMENTATION

High-quality patient care requires adequate documentation. There should be a permanent record of the MRI examination and its interpretation. Imaging of all appropriate areas, both normal and abnormal, should be recorded in a suitable archival format. If contrast material is administered during the MRI examination, the brand name of the contrast agent and the administered dose should be recorded and included in the permanent record of the MRI examination. An official interpretation (final report) of the MRI findings should be included in the patient's medical record regardless of where the study is performed. Retention of the MRI examination should be consistent both with clinical need and with relevant legal and local health care facility requirements.

Reporting should be in accordance with the ACR Practice Guideline for Communication of Diagnostic Imaging Findings.

VII. SAFETY GUIDELINES

Safety guidelines, practices, and policies must be written, enforced, reviewed, and documented at least annually by the supervising physician. These guidelines should take into consideration potential magnetic field interactions for ferromagnetic objects in the MRI environment [9]. They should also consider potential patient hazards (e.g., from magnetic field interactions, tissue heating, and induced electrical currents) and potential hazards posed by implanted objects and materials within the patient as well as other individuals in the MR environment [4-5].

A screening program should be implemented to assure appropriate and safe use of MR contrast material and to reduce the risk of nephrogenic systemic fibrosis (NSF) [10-11]. For further information on ACR screening recommendations see the ACR Manual on Contrast Media [12] and the ACR Guidance Document for Safe MR Practices [8]. Peer-reviewed literature pertaining to MR safety should be reviewed on a regular basis.

In pregnancy, gadolinium-based contrast agents (GBCAs) cross the placental barrier, enter the fetal circulation, and pass via the kidneys into the amniotic fluid. Although no definite adverse effects of GBCA administration on the human fetus have been documented, the potential bioeffects of fetal GBCA exposure are not well understood. GBCA administration should therefore be avoided during pregnancy unless no suitable alternative imaging is possible and the benefits of contrast administration outweigh the potential risk to the fetus. (See the ACR–SPR Practice Guideline for the Safe and Optimal Performance of Fetal MRI).

When GBCAs are administered to nursing women, a small amount of the contrast agent is excreted in the breast milk. It is unlikely that the minute amount of GBCA absorbed by a nursing infant's gastrointestinal tract will be harmful. If there is concern on the part of the referring physician, radiologist, or patient, the nursing mother can be advised to discard her breast milk for 24 hours after GBCA administration.

When contrast and/or sedation are necessary, they must be administered in accordance with institutional policy and state and federal law by a qualified practitioner with training in cardiopulmonary resuscitation [13]. (See the ACR–SPR Practice Guideline for the Use of Intravascular Contrast Media and the ACR–SIR Practice Guideline for Sedation/Analgesia.)

Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications. The equipment and medications should be monitored for inventory and drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population.

VIII. EQUIPMENT SPECIFICATIONS

The MRI equipment specifications and performance must meet all state and federal requirements. The requirements include, but are not limited to, specifications of maximum static magnetic field strength, maximum rate of change of magnetic field strength (dB/dt), maximum radiofrequency power deposition (specific absorption rate), and maximum acoustic noise levels.

IX. QUALITY CONTROL PROGRAM

A documented quality control program must be maintained at the MR site. Quality control testing should be conducted by the technologist and/or service engineer with review at least annually by the supervising physician and/or a medical physicist/MR scientist [14-16].

X. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR web site (http://www.acr.org/guidelines).

Equipment performance monitoring should be in accordance with the ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Magnetic Resonance Imaging (MRI) Equipment.

ACKNOWLEDGEMENTS

This guideline was revised according to the process described under the heading *The Process for Developing ACR Practice Guidelines and Technical Standards* on the ACR web site (http://www.acr.org/guidelines) by the ACR Commission on Body Imaging.

Principal Reviewer:
Jeffrey J. Brown, MD, MBA, FACR

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*Guidelines and standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For guidelines and standards published before 1999, the effective date was January 1 following the year in which the guideline or standard was amended, revised, or approved by the ACR Council.

Development Chronology for this Guideline
1992 (Resolution 14)
Amended 1995 (Resolution 53)
Revised 1996 (Resolution 1)
Revised 2000 (Resolution 16)
Revised 2001 (Resolution 12)
Amended 2002 (Resolution 2)
Revised 2006 (Resolution 15,16g,34,35,36)
Revised 2011 (Resolution 19)

Attachment C.Need.3.

Medical Care, PLLC

Proposed MRI Service area

Proposed service area includes; Carter, Johnson, Unicoi, Sullivan, and Washington counties in Tennessee

Attachment C.1.a. MRI Standards and Criteria 7.g.

The Hospitalist Company

ipc

March 7, 2013

To Whom It May Concern:

This is notification that the physicians of IPC of Tennessee provide hospital admissions and inpatient care for patients of **Medical Care, PLLC, 1500 W. Elk Avenue, Elizabethton, TN 37643**

IPC of Tennessee physicians are available to admit patients at the following facilities, 7 days per week, 24 hours per day. The IPC of Tennessee physician on call can be reached at the numbers listed below.

Johnson City Medical Center, Johnson City, TN	**(423) 854-2222**	**Franklin Transitional Care, Johnson City, TN**	**(888) 877-6975**
Holston Valley Medical Center, Kingsport, TN	**(888) 601-6073**	**Health South Rehabilitation Hospital, Kingsport, TN**	**(423) 246-7240**
Sycamore Shoals Hospital, Elizabethton, TN	**(423) 410-1955**	**Quillen Rehabilitation Hospital, Johnson City, TN**	**(423) 952-1700**
Bristol Regional Medical Center, Bristol, TN	**(888) 214-9443**	**Health South Rehabilitation Hospital, Bristol, VA**	**(276) 642-7908**

Following is a list of physicians on staff at IPC of TN.

Last Name	First Name	NPI	Last Name	First Name	NPI
Abu-Zeitoon MD	Rawan	1265621072	Mahboob, MD	Rashid	1659356335
Adams, DO	Stephanie A.	1023289493	Mann, MD	John	1104811694
Aimua, MD	Benedict E.	1962674424	Martin, MD	Jei	1033104047
Ali, MD	Muhammad	1265626279	Meade, DO	Farida E.	1174717235
Belagode, MD	Vinaya S	1518048172	Nazarov, MD	Vitaly	1760469084
Clark MD	Vivian	1205889508	Obuekwe, MD	Uzoma	1992901409
Collnger MD	J.W.	1245283886	Ozuah, MD	Uchenna	1578883377
Colinger DO	Jason	1609829241	Paris, MD	Claire	1063465128
Daniel DO	John	1013987023	Pickstock, MD	Janet G.	1215914528
Diaz Valdes, MD	Sergio A.	1417138439	Porter, MD	Keith G.	1821036179
Donovan, MD	Brian P	1598741787	Quinn, MD	Donald R.	1447219688
Garrido, MD	Jose A.	1982640140	Sawaf, DO	John N.	1346347358
Gonce, MD	Joel	1114920188	Singh, MD	Parminderjit	1396903126
Gutta, MD	Veerendra	1457362162	Squires MD	Anne Charlotte	1871586917
Holt, MD	Jacob E.	1194831636	Starr, MD	Dennis	1477727816
Jackson, MD	Richard	1457359770	Theerathorn, MD	Pitchar	1548223084
Jastan, MD	Rasmiyah	1740474527	Tountcheva, MD	Dimka M.	1316924665
Jurdi, MD	Makram	1124281894	Udoeyop, MD	U. Walter	1730166083
Kharalkar, MD	Shweta	1851585996	Vashsit MD	Amit	1598950644
Kopparapu MD	Anil	1487891401	Walker, MD	Robert W.	1902877137
Lamb MD	Ray	1497858575			

If you have any questions, please contact Sharon Alvis at (423) 282-1480 extension 314.

Sincerely,

Louis Collier

Louis Collier, Director of Operations, TN Region

Attachment C Economic Feasibility 1.

PROJECT COSTS CHART

A.	Construction and equipment acquired by purchase:	
1.	Architectural and Engineering Fees	0
2.	Legal, Administrative (Excluding CON Filing Fee), Consultant Fees	5,000
3.	Acquisition of Site	0
4.	Preparation of Site	0
5.	Construction Costs	0
6.	Contingency Fund	0
7.	Fixed Equipment (Not included in Construction Contract)	0
8.	Moveable Equipment (List all equipment over $50,000)	0
9.	Other (Specify) _____	0
B.	Acquisition by gift, donation, or lease:	
1.	Facility (inclusive of building and land)	
2.	Building only	
3.	Land only	
4.	Equipment (Specify) MRI	1,597,440
5.	Other (Specify) facility lockers	2,499.60
C.	Financing Costs and Fees:	
1.	Interim Financing	0
2.	Underwriting Costs	0
3.	Reserve for One Year's Debt Service	0
4.	Other (Specify) _____	0
D.	Estimated Project Cost (A+B+C)	1,604,939.60
E.	CON Filing Fee	3,611.11
F.	Total Estimated Project Cost (D+E)	
	TOTAL	1,608,550.71

Attachment C Economic Feasibility 4.

HISTORICAL DATA CHART

Give information for the last *three (3)* years for which complete data are available for the facility or agency. The fiscal year begins in January (Month).

	Year 2012	Year 2013	Year 2014
A. Utilization Data (Specify unit of measure)	254,696	284,150	326,782
B. Revenue from Services to Patients			
1. Inpatient Services	$	$	$
2. Outpatient Services	18,228,256	20,207,113	26,608,993
3. Emergency Services			
4. Other Operating Revenue (Specify)_____			
Gross Operating Revenue	$18,228,256	$20,207,113	$26,608,993
C. Deductions from Gross Operating Revenue			
1. Contractual Adjustments	$8,403,226	$8,802,061	$12,331,221
2. Provision for Charity Care	747,358	782,829	1,096,702
3. Provisions for Bad Debt	1,044,229	1,093,790	1,532,342
Total Deductions	$10,194,813	$10,678,681	$14,960,266
NET OPERATING REVENUE	$8,033,443	$9,528,432	$11,648,727
D. Operating Expenses			
1. Salaries and Wages	$2,290,216	$2,661,449	$3,034,245
2. Physician's Salaries and Wages	2,106,806	2,313,816	2,868,960
3. Supplies	260,316	531,534	560,276
4. Taxes	249,982	537,867	538,540
5. Depreciation	195,462	797,784	955,641
6. Rent			
7. Interest, other than Capital			
8. Management Fees:			
a. Fees to Affiliates	2,624,563	2,704,580	3,556,232
b. Fees to Non-Affiliates			
9. Other Expenses (Specify) _____			
Total Operating Expenses	$7,727,345	$9,547,030	$11,513,894
E. Other Revenue (Expenses) – Net (Specify)	$	$	$
NET OPERATING INCOME (LOSS)	$306,098	$(18,598)	$134,833
F. Capital Expenditures			
1. Retirement of Principal	$(4,404,830)	$(381,063)	$(196,147)
2. Interest	351,847	440,289	422,739
Total Capital Expenditures	$(4,052,983)	$59,226	$226,592
NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES	$4,359,081	$(77,824)	$(91,759)

PROJECTED DATA CHART

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in January (Month).

		Year 2015	Year 2016
A.	Utilization Data (Specify unit of measure)	726 scans	762 scans
B.	Revenue from Services to Patients (1,584.55 per scan)		
	1. Inpatient Services	$	$
	2. Outpatient Services	1,150,383.30	1,207,427.10
	3. Emergency Services		
	4. Other Operating Revenue (Specify)_____		
	Gross Operating Revenue	$1,150,383.30	$1,207,427.10
C.	Deductions from Gross Operating Revenue (691.89 per scan)		
	1. Contractual Adjustments	$ 452,080	$ 474,497.40
	2. Provision for Charity Care	20,095.68	21,092.16
	3. Provisions for Bad Debt	30,136.26	31,630.62
	Total Deductions	$ 502,311.94	$ 527,220.18
NET OPERATING REVENUE		$ 648,071.16	$ 680,207.00
D.	Operating Expenses		
	1. Salaries and Wages	$ 33,150	$ 33,150
	2. Physician's Salaries and Wages	50,820	53,340
	3. Supplies	18,000	18,900
	4. Taxes		
	5. Depreciation		
	6. Rent	159,993.96	159,993.96
	7. Interest, other than Capital		
	8. Management Fees:		
	a. Fees to Affiliates		
	b. Fees to Non-Affiliates		
	9. Other Expenses (Specify) _____		
	Total Operating Expenses	$ 261,963.96	$ 265,383.96
E.	Other Revenue (Expenses) -- Net (Specify)	$	$
NET OPERATING INCOME (LOSS)		$ 386,107.20	$ 414,823.04
F.	Capital Expenditures		
	1. Retirement of Principal	$	$
	2. Interest		
	Total Capital Expenditures	$	$
NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES		$ 386,107.20	$ 414,823.04

Attachment C Economic Feasibility 10.

PINE PALMS MANAGEMENT, LLC
AND MEDICAL CARE, PLLC

Combined Financial Statements

Years Ended December 31, 2014 and 2013

Draft
For Discussion Purposes Only

Table of Contents

PINE PALMS MANAGEMENT, LLC and MEDICAL CARE, PLLC

Combined Statements of Assets, Liabilities and Members' Deficit -

Income Tax Basis

December 31, 2014 and 2013

	2014	2013
ASSETS		
Current Assets		
Cash	$ -	$ 199,929
Due from officers	-	77,289
Current portion of note receivable	5,706	5,291
Other current assets	3,370	1,483
Total current assets	9,076	283,993
Property and Equipment		
Land	1,161,627	1,396,093
Land Improvements	1,748,045	1,604,045
Buildings	6,359,313	5,972,309
Furniture, fixtures and equipment	3,584,088	3,158,520
Software	54,800	50,784
Accumulated depreciation and amortization	(5,318,559)	(4,427,818)
	7,589,313	7,753,933
Other Assets		
Due from related party	-	48,500
Long-term portion of note receivable	78,012	83,718
Deposits	-	91,795
	78,012	224,013
Total assets	$ 7,676,401	$ 8,261,939
LIABILITIES AND MEMBERS' DEFICIT		
Current Liabilities		
Outstanding checks in excess of bank balance	$ 53,382	$ -
Lines of credit	-	60,108
Other current liabilities	35,358	1,213
Current portion of notes payable	373,190	333,326
Total current liabilities	461,929	394,647
Long-term Debt		
Notes payable, net of current portion shown above	8,668,222	8,485,773
Total liabilities	9,130,151	8,880,420
Members' Deficit	(1,453,750)	(618,481)
Total liabilities and members' deficit	$ 7,676,401	$ 8,261,939

The accompanying notes are an integral part of the combined financial statements.

PINE PALMS MANAGEMENT, LLC and MEDICAL CARE, PLLC

Combined Statements of Revenue, Expenses and Members' Deficit -

Income Tax Basis

For the years ended December 31, 2014 and 2013

	2014	2013
Income		
Fees, net	$ 11,495,018	$ 9,535,951
Rental income	274,102	245,619
Reimbursments	339,132	151,270
Other income	21,909	15,381
	12,130,160	9,948,221
Expenses		
Salaries & wages	4,698,160	3,751,249
Employee benefits	394,322	388,242
Payroll taxes	342,284	299,356
Continuing education	36,669	49,375
Medical & laboratory supplies	2,591,976	1,883,173
Depreciation and amortization	955,641	797,784
Outside services	341,289	293,093
Taxes & Licenses	196,255	238,512
Utilities & Telephone	246,120	233,184
Office supplies and postage	184,723	173,358
Professional Fees	236,012	146,311
Repairs and maintenance	83,923	126,945
Insurance expense	107,005	103,873
Licenses & permits	80,420	45,070
Contract labor	28,970	33,515
Supplies	7,004	18,083
Business gifts & entertainment	12,800	15,306
Travel	6,998	14,453
Other	30,717	18,275
Members' Compensation		
Guaranteed Payments	817,966	808,638
Retirement	86,251	-
Health Insurance	44,611	48,704
Life Insurance	44,167	44,167
Total Operating Expenses	11,574,284	9,530,666
Net Operating Income (Deficit)	555,876	417,555
Interest expense	(422,739)	(440,289)
Net Income (Loss)	133,136	(22,734)
Members' Equity (Deficit) at beginning of year	(618,481)	(85,747)
Members' withdrawals	[illegible]	(510,000)
Members' Deficit at end of year	(1,453,750)	(618,481)

The accompanying notes are an integral part of the combined financial statements.

PINE PALMS MANAGEMENT, LLC and MEDICAL CARE, PLLC

Combined Statements of Cash Flows -

Income Tax Basis

For the years ended December 31, 2014 and 2013

	2014	2013
Cash Flows From Operating Activities		
Net income (loss)	$ 133,136	$ (22,734)
Adjustments to reconcile net income to net cash flows from operating activities:		
Depreciation and amortization	955,641	797,784
Gain on sale of land	-	-
Changes in operating assets and liabilities:		
(Increase)/decrease in other current assets	(1,886)	4,586
Increase/(decrease) in accrued expenses	34,144	1,212
(Increase)/decrease in due from related party	48,500	-
(Increase)/decrease in deposits	91,795	(91,795)
Net cash provided by operating activities	1,261,330	689,053
Cash Flows From Investing Activities		
Purchase of property and equipment	(1,065,131)	(879,223)
Proceeds from sale of land	274,110	165,215
Payments received on note receivable	5,291	5,224
Loan repayments received from officers	77,289	15,203
Net cash used in investing activities	(708,441)	(693,581)
Cash Flows From Financing Activities		
Change in checks in excess of bank balance	53,382	-
Cash distributions to members	(968,405)	(510,000)
Repayment of loan to officer	-	(200,000)
Net change in lines of credit	(524,935)	(422,612)
Proceeds from notes payable	6,900,000	1,372,632
Repayments on notes payable	(6,212,860)	(369,989)
Net cash used in financing activities	(752,818)	(129,969)
Net decrease in cash	(199,929)	(134,497)
Cash at the Beginning of the Period	199,929	334,426
Cash at the End of the Period	$ -	$ 199,929
Supplemental Disclosures of Cash Flow Information		
Cash paid for interest	$ 422,739	$ 493,335
Cash paid for income taxes	$ -	$ -

The accompanying notes are an integral part of the combined financial statements

NOTE 1 – NATURE OF OPERATIONS

The combined financial statements include financial statement information of Pine Palms Management, LLC, and Medical Care, PLLC (collectively referred to as the "Company"). These Companies were formed as two separate limited liability companies under the laws of the State of Tennessee. Pine Palms Management, LLC was formed for the purpose of providing management services to Medical Care, PLLC. Medical Care, PLLC was formed for the purposes of providing medical services.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLOCIES

Basis of Consolidation
As described above, the financial statements include the activity of Pine Palms Management, LLC and Medical Care, PLLC. All significant intercompany transactions have been eliminated.

Basis of Accounting
The Company prepares their financial statements in conformity with methods of accounting that it considers appropriate for Federal income tax reporting, which is a comprehensive basis of accounting other than generally accepted accounting principles. This method is the tax, modified cash basis of accounting which includes the recognition of income when cash is received and the recognition of expenses when cash is disbursed. Generally accepted accounting principles require income to be recognized when earned and expenses recognized when incurred. Additionally, tax reporting allows for depreciation of capital assets over statutory periods rather than their useful lives, as well as electing to expense depreciable assets placed in service during the year in accordance with the maximum allowable under Section 179 of the Internal Revenue Code.

Use of Estimates
The preparation of financial statements in conformity with the income tax basis of accounting requires management to make estimates and assumptions that affect reported amounts and disclosures. Accordingly, actual results could differ from those estimates.

Cash and cash equivalents
For the purpose of the statement of cash flows, the Company considers money market accounts and highly liquid securities with maturities of 90 days or less to be cash equivalents.

Property and Equipment
Property and Equipment are recorded at cost. Depreciation is computed using straight-line and accelerated methods over statutory lives that range from 5 to 39 years. The Company also utilizes both Section 179 of the Internal Revenue Code which allows for expensing of qualified depreciable assets in the year of acquisition and bonus depreciation which allows for an additional 50% to 100% of the basis in depreciable assets to be expensed in the year of acquisition. Additional depreciation using both Section 179 and bonus depreciation was $495,651 and $256,385 in 2014 and 2013, respectively.

In 2013, the Company completed the construction of a new office building. Pursuant to IRS regulations, the Company capitalized interest costs incurred on the construction loan during the construction of the building. Capitalized interest costs were $53,046 for 2013.

Expenditures for maintenance and repairs are expensed when incurred. Expenditures for renewals or betterments are capitalized. Gains and losses from dispositions are included in income when realized.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLOCIES, continued

Income Taxes

The companies are treated as partnerships for federal income tax purposes. Accordingly, federal income taxes are not payable by, or provided for in these financial statements. Members are taxed individually on their shares of the Company's earnings. The Company's net income or loss is allocated among the members in accordance with the operating agreement of the separate companies. The financial statements do not reflect a provision for income taxes.

NOTE 3 – NOTE RECEIVABLE

In connection with the recruitment of a physician, the Company loaned a physician $110,000 for the purchase of a personal residence. The outstanding note receivable balance was $83,718 and $89,009 as of December 31, 2014 and 2013, respectively. The loan is repayable in 180 monthly payments of $988.71 (including interest at 7%), is secured by a Deed of Trust on the residence and matures in March 2026. Interest income earned on this note was $6,087 and $6,539 for the years ended December 31, 2014 and 2013, respectively, and is recorded on the statement of revenue, expenses, and members' deficit in other income.

NOTE 4 – REFINANCING

In February 2014, the Company refinanced a mortgage incurred for the construction of real property. This refinance included the pay-off of a construction note with a balance of $5,794,751 at December 31, 2013 and the pay-off of an existing line of credit with a balance of $464,827 at December 31, 2013. The Company paid additional fees and incurred additional borrowings which resulted in a new mortgage of $6,750,000. The balances in notes payable and the line of credit at December 31, 2013 have been reclassified in the statement of assets, liabilities, and members' deficit as well as Note 5 and 6 below, to reflect the current and long-term liabilities after this refinancing.

NOTE 5 – LINES OF CREDIT

During 2014 the Company entered into a line of credit agreement with a financial institution in the amount of $1,500,000. This line of credit bears interest at the prime rate with a floor of 3.25% and matures on March 5, 2016. The line of credit is secured by substantially all the assets of the Company and personal guarantees of the members. As of December 31, 2014 there was no outstanding balance on this line of credit.

At December 31, 2013, the Company had line of credit agreements with financial institutions of $670,000. The first line of credit for $500,000 with an outstanding balance of $464,827 at December 31, 2013 was included in the refinancing described above and has been reclassified and included in the mortgage note payable. The second line of credit of $170,000, bore interest at prime plus .75%, and had an outstanding balance of $60,108 at December 31, 2013. This line of credit matured during 2014, was paid in full, and was not renewed.

NOTE 6 – LONG-TERM DEBT

Long term debt consisted of the following at December 31, 2014 and 2013:

	2014	2013
Mortage payable with a total balance of $6,750,000, repayable in 59 monthly payments of $30,613 including interest at libor plus 2.4% (2.56% at December 31, 2014 and 2013, respectively) and a final payment of approximately $5.75 million in March 2019. This note is secured by a building and the personal guarantees of the members.	$ 6,605,350	$ 6,259,578
Installment note payable repayable in 59 monthly installments of $18,700 including interest at 4.3% and a final payment of aproximately $1.8 million in October 2018. This note is collaterilzed by equipment and by the personal guarantees of the members	2,326,558	2,446,706
Installment note payable in monthly installments of $4,344 including interest at 2.65% through March 2017. This note is collaterilzed by equipment and by the personal guarantees of the members	109,503	-
Installment note payable repayable in monthly installments of $4,770 including interest at 5.5% through December 2015. This note is collaterilzed by equipment and by the personal guarantees of the members	-	112,815
TOTAL	9,041,411	8,819,099
Less current maturites	(373,190)	(333,326)
Long-term debt	$ 8,668,221	$ 8,485,773

NOTE 6 – LONG-TERM DEBT, continued

Maturities of long-term debt are as follows:

2015	373,190
2016	389,381
2017	362,345
2018	2,145,300
2019	5,771,195
Therafter	-
	$ 9,041,411

NOTE 7 – RELATED PARTY TRANSACTIONS

The companies receive computer supplies and support services from Medical Software Solutions, LLC (MSS). The members of the companies are also the owners of MSS. The companies paid MSS $111,846 and $44,900 during the years ended December 31, 2014 and 2013, respectively. In addition, MSS owed the company $0 and $48,500 at December 31, 2014 and 2013, respectively.

NOTE 8 – SUBSEQUENT EVENTS

The Company has evaluated subsequent events through May 1, 2015, the date which the financial statements were available to be issued. No events have occurred, other than the subsequent refinancing, which would have a material effect on the financial statements of the Companies as of that date.

NOTE 9 – CONCENTRATIONS OF RISK

The Company maintains its cash deposits in several financial institutions located in Tennessee. Balances of deposits to these accounts may at times exceed the government insured limits. As of Management believes exposure of loss is minimal and any actual loss is unlikely.

The Company provides medical services for clients in Northeastern Tennessee. Payment for these services is received from various sources such as Medicare and third party health insurance providers. Changes in reimbursement rates could have a negative impact on the operations of the Company.

NOTE 10 – RETIREMENT PLAN

The Company sponsors a SIMPLE IRA retirement plan that allows for employee contributions of up to $14,500 annually and matching contributions of up to 3% of participating employee's compensation. The Company's matching contributions for the years ended December 31, 2014 and 2013 were $96,020 and $65,735, respectively.

PROJECT COMPLETION FORECAST CHART

PROJECT COMPLETION FORECAST CHART

Enter the Agency projected Initial Decision date, as published in T.C.A. § 68-11-1609(c): August 26, 2015

Assuming the CON approval becomes the final agency action on that date; indicate the number of days **from the above agency decision date** to each phase of the completion forecast.

Phase	DAYS REQUIRED	Anticipated Date (MONTH/YEAR)
1. Architectural and engineering contract signed		
2. Construction documents approved by the Tennessee Department of Health		
3. Construction contract signed		
4. Building permit secured		
5. Site preparation completed		
6. Building construction commenced		
7. Construction 40% complete		
8. Construction 80% complete		
9. Construction 100% complete (approved for occupancy		
10. *Issuance of license		
11. *Initiation of service	0	August 26, 2015
12. Final Architectural Certification of Payment		
13. Final Project Report Form (HF0055)		

* **For projects that do NOT involve construction or renovation: Please complete items 10 and 11 only.**

Note: **If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.**

AFFIDAVIT

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF Carter

Steven Hopland, being first duly sworn, says that he/she is the applicant named in this application or his/her lawful agent, that this project will be completed in accordance with the application, that the applicant has read the directions to this application, the Tennessee Health Services and Development Agency and T.C.A. § 68-11-1601, *et seq.*, and that the responses to questions in this application or any other questions deemed appropriate by the Tennessee Health Services and Development Agency are true and complete.

Signature/Title

Sworn to and subscribed before me this the 11th day of May, 2015, a Notary Public in and for the County of Carter, State of Tennessee.

NOTARY PUBLIC

My Commission expires 08-07-2018.

SHIRLEY M. HONEYCUTT STATE OF TENNESSEE NOTARY PUBLIC COUNTY OF CARTER

HF-0056
Revised 7/02 - All forms prior to this date are obsolete

FARRIS BOBANGO, PLC

ATTORNEYS AT LAW

Nashville · Memphis

HISTORIC CASTNER-KNOTT BUILDING
618 CHURCH STREET, SUITE 300
NASHVILLE, TENNESSEE 37219

(615) 726-1200 telephone · (615) 726-1776 facsimile

Rachel C. Nelley
rnelley@farris-law.com

Direct Dial:
(615) 687-4231

May 13, 2015

Ms. Melanie M. Hill
Executive Director
Health Services and Development Agency
Andrew Jackson Building, Ninth Floor
502 Deaderick Street Nashville, TN 37243

RE: Application for Certificate of Need of Medical Care, PLLC and Request to be Placed on Consent Calendar

Dear Ms. Hill:

Enclosed please find one (1) original and two (2) copies of the application for certificate of need of my client, Medical Care, PLLC, along with a check for the filing fee in the amount of $3,611.11.

As we do not anticipate any opposition to the application, we respectfully request that the application be placed on the consent calendar.

Thank you in advance for your assistance.

Sincerely,

Rachel C. Nelley

RCN/

cc: Steve Hopland

State of Tennessee
Health Services and Development Agency
Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

June 1, 2015

Rachel C. Nelley, Esq.
Farris Bobango, PLC
618 Church St
Elizabethton, TN 37643

RE: Certificate of Need Application -- Medical Care PLLC - CN1505-018
CONSENT CALENDAR -A multi-specialty medical group seeks approval to initiate MRI services for use by its physicians and patients. The project focuses on a shared equipment and services arrangement with Mountain States Health Alliance d/b/a Sycamore Shoals Hospital for the use of an existing MRI unit located on the hospital campus on a block time basis, initially 12 hours per week. The project cost is $1,608,550.71.

Dear Ms. Nelley:

This is to acknowledge the receipt of supplemental information to your application for a Certificate of Need. Please be advised that your application is now considered to be complete by this office.

Your application is being forwarded to Trent Sansing at the Tennessee Department of Health for Certificate of Need review by the Division of Policy, Planning and Assessment. You may be contacted by Mr. Sansing or someone from his office for additional clarification while the application is under review by the Department. Mr. Sansing's contact information is Trent.Sansing@tn.gov or 615-253-4702.

In accordance with Tennessee Code Annotated, §68-11-1601, et seq., as amended by Public Chapter 780, the 30-day review cycle for **CONSENT CALENDAR** for this project will begin on June 1, 2015. The first thirty (30) days of the cycle are assigned to the Department of Health, during which time a public hearing may be held on your application. You will be contacted by a representative from this Agency to establish the date, time and place of the hearing should one be requested. At the end of the thirty (30)-day period, a written report from the Department of Health or its representative will be forwarded to this office for Agency review within the thirty (30)-day period immediately following. You will receive a copy of their findings. The Health Services and Development Agency will review your application on August 26, 2015.

Any communication regarding projects under consideration by the Health Services and Development Agency shall be in accordance with T.C.A. § 68-11-1607(d):

(3) No communications are permitted with the members of the agency once the Letter of Intent initiating the application process is filed with the agency. Communications between agency members and agency staff shall not be prohibited. Any communication received by an agency member from a person unrelated to the applicant or party opposing the application shall be reported to the Executive Director and a written summary of such communication shall be made part of the certificate of need file.

(4) All communications between the contact person or legal counsel for the applicant and the Executive Director or agency staff after an application is deemed complete and placed in the review cycle are prohibited unless submitted in writing or confirmed in writing and made part of the certificate of need application file. Communications for the purposes of clarification of facts and issues that may arise after an application has been deemed complete and initiated by the Executive Director or agency staff are not prohibited.

Should you have questions or require additional information, please contact me.

Sincerely,

Melanie M. Hill
Executive Director

cc: Trent Sansing, TDH/Health Statistics, PPA

State of Tennessee
Health Services and Development Agency
Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

MEMORANDUM

TO: Trent Sansing, CON Director
Office of Policy, Planning and Assessment
Division of Health Statistics
Andrew Johnson Tower, 2nd Floor
710 James Robertson Parkway
Nashville, Tennessee 37243

FROM: Melanie M. Hill
Executive Director

DATE: June 1, 2015

RE: Certificate of Need Application
Medical Care PLLC - CN1505-018
CONSENT CALENDAR

Please find enclosed an application for a Certificate of Need for the above-referenced project.

This application has undergone initial review by this office and has been deemed complete. It is being forwarded to your agency for a Consent Calendar 30-day review period to begin on June 1, 2015 and end on July 1, 2015.

Should there be any questions regarding this application or the review cycle, please contact this office.

Enclosure

cc: Rachel C. Nelley, Esq.

State of Tennessee
Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

LETTER OF INTENT

The Publication of Intent is to be published in the Elizabethton Star (Name of Newspaper) which is a newspaper of general circulation in Carter (County), Tennessee, on or before May 8 (Month / day), 2015 (Year), for one day.

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 *et seq.*, and the Rules of the Health Services and Development Agency, that:

Medical Care, PLLC (Name of Applicant) professional private practice (Facility Type-Existing)

owned by: Medical Care PLLC with an ownership type of professional limited liability company

and to be managed by: Pine Palms Management, LLC intends to file an application for a Certificate of Need for [PROJECT DESCRIPTION BEGINS HERE]: initiation of magnetic resonance imaging (MRI) services to its patients by sharing existing MRI equipment located at Sycamore Shoals Hospital at 1501 W. Elk Ave. in Elizabethton, Carter County, TN. The project costs are $1,608,550.71. The project does not include the acquisition of major medical equipment, will not require facility licensure and affects no licensed inpatient bed complements.

The anticipated date of filing the application is: May 13, 2015

The contact person for this project is Rachel C. Nelley, Esq. (Contact Name) Attorney (Title)

who may be reached at: Farris Bobango, PLC, 618 Church Street, Suite 300 (Company Name) (Address)

Nashville (City)	TN (State)	37219 (Zip Code)	(615) / 726-1200 (Area Code / Phone Number)

Rachel C. Nelley (Signature) May 8, 2015 (Date) rnelley@farris-law.com (E-mail Address)

The Letter of Intent must be filed in triplicate and received between the first and the tenth day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

SUPPLEMENTAL - #2 ORIGINAL

Medical Care, PLLC

CN1505-018

SUPPLEMENTAL- 2

May 29, 2015
10.15am

FARRIS BOBANGO, PLC

ATTORNEYS AT LAW

Nashville · Memphis

HISTORIC CASTNER-KNOTT BUILDING
618 CHURCH STREET, SUITE 300
NASHVILLE, TENNESSEE 37219

(615) 726-1200 telephone · (615) 726-1776 facsimile

Rachel C. Nelley
rnelley@farris-law.com

Direct Dial:
(615) 687-4231

May 29, 2015

Mr. Jeff Grimm
Health Examiner
Health Services and Development Agency
Andrew Jackson Building, Ninth Floor
502 Deaderick Street Nashville, TN 37243

RE: Certificate of Need Application CN1505-018
Medical Care, PLLC – Initiation of Shared MRI Service for use by Patients of the Practice

Dear Mr. Grimm:

This letter will serve to follow up the filing of the above-referenced certificate of need application and is submitted as a second supplemental response to your e-mailed correspondence dated May 28, 2015, wherein additional information or clarification was requested.

1. **Section B, Project Description, Item II.E.**
The cost of the applicant's 10-year lease payments was identified as $1,599,939.00 on pages 11 and 30 of the application. However, the lease cost was shown as $1,597,400.00 on line B.4 of the Project Costs Chart in the application. Accordingly, it appears that the correct amount for the 10 year lease cost that applies to this project is $1,599,939.00. Please clarify.

Response: The Applicant's figures on the Project Costs Chart as originally submitted were correct. Attached is a version of that cost chart with the same figures that were originally submitted that also includes the mathematical calculations that the Applicant used to arrive at its original figures. On pages 11 and 13 of the application, the total of the lease payments (MRI plus lockers) over 10 years is $1,599,939.60 because Medical Care added $159,744 for MRI + 249.96 for lockers =159,993.96 to arrive at annual costs then multiplied the figure by 10 to arrive at the 10 year lease term cost of 1,599,939.60. On the Project Costs Chart, MRI and lockers are listed separately. Thus, ($249.96 annually for lockers x 10 = $2,499.60 for lockers over the term) plus ($159,744

annually for MRI x 10 = $1,597,440 over the term) = 1,599,939.60 total term cost (NOT 1,599,939+2499.60 as you suggest; your suggestion includes the cost of the lockers twice).

2. **Section C, Economic Feasibility, Item 1 (Project Cost Chart)**
The applicant provided a copy of a detailed equipment vendor quotation in the 5/28/15 supplemental response. This documentation sufficiently identifies the MRI unit's Fair Market Value (FMV) for CON application purposes as $1,830,173.00, inclusive of a 60 month service agreement cost. However, when prorated by 30% for the applicant's shared use of the hospital's MRI unit, the FMV actually decreases to approximately $549,051.90. As such, please note that the estimated FMV should not be used in the Project Costs Chart for CON purposes since it is lower than the applicant's expected 10 year lease cost.

For the reasons described above, please provide a revised Project Cost Chart with corrected entries for the following line items of the chart:

Line B.4 (equipment lease cost)
Line D (estimated project cost)
Line E (CON filing fee)
Line F (total estimated project cost with filing fee)

Response: For the reasons described in response to #1 hereinabove, the original Project Cost Chart in the application should remain in place. HSDA can ignore the revised Project Cost Chart submitted with the Applicant's response to HSDA's First Request for Supplemental Information.

In your response, please note that the new filing fee should change to $3,616.74, a difference of $5.63 from the original filing fee. Please remit the additional $5.63 filing fee amount in the form of a check or money order payable to HSDA.

Response: For the reasons stated herein, the original filing fee of $3611.11 was correct.

Sincerely,

Rachel C. Nelley

RCN/rwc
Encl.
cc: Steve Hopland

SUPPLEMENTAL- 2

May 29, 2015
10.15am

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF Davidson

NAME OF FACILITY: Medical Care PLLC

I, RACHEL C. NELLEY, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

Rachel C. Nelley attorney
Signature/Title

Sworn to and subscribed before me, a Notary Public, this the 29th day of May, 2015, witness my hand at office in the County of Davidson, State of Tennessee.

Whitney Cantrell
NOTARY PUBLIC

My commission expires January 9, 2018.

WHITNEY CANTRELL
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY
My Commission Expires JAN. 9, 2018

HF-0043

Revised 7/02

SUPPLEMENTAL- 2

May 29, 2015
10.15am

PROJECT COSTS CHART

A.	Construction and equipment acquired by purchase:	
1.	Architectural and Engineering Fees	0
2.	Legal, Administrative (Excluding CON Filing Fee), Consultant Fees	5,000
3.	Acquisition of Site	0
4.	Preparation of Site	0
5.	Construction Costs	0
6.	Contingency Fund	0
7.	Fixed Equipment (Not included in Construction Contract)	0
8.	Moveable Equipment (List all equipment over $50,000)	0
9.	Other (Specify) _____	0
B.	Acquisition by gift, donation, or lease:	
1.	Facility (inclusive of building and land)	
2.	Building only	
3.	Land only	
4.	Equipment (Specify) MRI 159,744/yr x 10 yr lease term	1,597,440
5.	Other (Specify) facility lockers x 10 yr lease term	2,499.60
		total = 1,599,939.60
C.	Financing Costs and Fees:	
1.	Interim Financing	0
2.	Underwriting Costs	0
3.	Reserve for One Year's Debt Service	0
4.	Other (Specify) _____	0
D.	Estimated Project Cost (A+B+C)	1,604,939.60
E.	CON Filing Fee	3,611.11
F.	Total Estimated Project Cost (D+E)	
	TOTAL	1,608,550.71

State of Tennessee
Health Services and Development Agency
Andrew Jackson Building, 9th Floor
www.tn.gov/hsda Phone: 615-741-2364/Fax: 615-741-9884

May 19, 2015

Rachel C. Nelley, Attorney
Farris Bobango PLC
618 Church Street, Suite 300
Nashville, TN 37219

RE: Certificate of Need Application CN1505-018
Medical Care, PLLC – Initiation of Shared MRI Service for use by Patients of the Practice

Dear Ms. Neeley,
This will acknowledge our May 13, 2015 receipt of your Consent Calendar Request regarding your application for a Certificate of Need to initiate MRI services for the patients of Medical Care, PLLC through a shared services and equipment agreement with Mountain States Health alliance d/b/a Sycamore Shoals Hospital to block leased time on the existing MRI unit located on the hospital's campus in Elizabethton (Carter County), Tennessee. As part of the project, the proposed MRI service will be operated as an ancillary service of Medical Care, PLLC limited to the use of its patients.

Several items were found which need clarification or additional discussion. Please review the list of questions below and address them as indicated. The questions have been keyed to the application form for your convenience. I should emphasize that an application cannot be deemed complete and the review cycle begun until all questions have been answered and furnished to this office.

Please submit responses in triplicate by 3:00 PM, May 22, 2015. If the supplemental information requested in this letter is not submitted by or before this time, then consideration of this application may be delayed into a later review cycle.

---

1. **Section A, Applicant Profile, Item 1**
   As the contact for the applicant may be aware, all approved Certificates of Need are site specific. Since the proposed shared MRI is located on the campus of Sycamore Shoals Hospital located at 1501 West Elk Avenue in Elizabethton, TN, please revise the address provided and submit in a replacement page 1-R.

2. **Section A, Applicant Profile, Item 5 (Manager)**

   The information for the management operating entity, including a copy of the Management Services Agreement in the attachments, is noted

   Please provide a copy of the manager's current registration with the TN Secretary of State office.

Review of the Management Services Agreement for the 5 year period ending April 2015 revealed that the agreement was null and void after December 31, 2013. Given the proposal to share use of the MRI unit at Sycamore Shoals Hospital, what are the major features of the new agreement between the applicant and the manager as it relates to primary responsibilities, term and payment for services? Please clarify. As a suggestion, the applicant should provide a copy of a revised draft agreement or a letter of intent that identifies the key terms of the proposed arrangement. In your response, please also describe the manager's responsibility for providing medical and clinical supervision support for the applicant's use of the hospital's MRI unit on a block time basis.

What provisions, if any, apply to the applicant's plans to use Pine Palm Management, LLC as the manager of its proposed shared MRI service subject to prior approval by hospital? Should the manager be a party to the "Licensure Agreement" (with 12/10/14 amendment) between the hospital and applicant? If so, what are the key provisions that might apply in this regard? Please explain.

3. **Section A, Applicant Profile, Item 6**
Other than the "License Agreement" provided in the attachments, what additional documentation can be provided to support hospital's ownership of the premises and MRI equipment such that its authority to contract with the applicant for these items can be fully appreciated?

4. **Section B, Applicant Profile, Item 13 and Section C, Economic Feasibility, Item 6.B**

The response is noted. The applicant states that professional fees for MRI interpretation services will be billed by contracted radiologists of National Diagnostic Imaging of Beachwood, Ohio. As such, what assurances apply such that the radiologists will hold Medicare and Medicaid provider certification and will be contracted with the same TennCare MCO plans as the applicant? Please briefly discuss the arrangements planned in this regard.

5. **Section B, Project Description, Item II.A. and Item II.E.**

Item II.A -Please briefly describe general features of the hospital and dedicated space of the MRI unit such as floor location, primary patient entrances, exits, clinical/admin support space, patient waiting, and other hospital departments on same floor closest to the MRI area.

The applicant notes that the hospital has acquired a new MRI unit (1.5 Tesla Toshiba Titan) to replace its existing 1.5 Tesla GE Signa unit by June 1, 2015. Please briefly describe the participation of licensed architects, structural engineers or other qualified professionals in review and approval of the hospital's plans for installation of the replacement unit.

Per the applicant, it appears that interim use of a mobile MRI unit may be necessary should the new fixed 1.5 Tesla Toshiba unit not be installed & operational within the June 1, 2015 timeframe desired. Please describe the mobile equipment & docking facilities available at the hospital to operate a mobile MRI should this need arise.

Item II.E:
1.a.1 - Fixed Site Units - Expected Useful Life - please also identify the manufacture date of the hospital's new 1.5 Tesla Toshiba MRI unit that will replace the existing GE unit in June 2015.

2.a, 2.d and 2.e – Mobile Units – as the applicant has indicated, a mobile unit at the hospital may need to be used if the hospital's replacement unit is not available. If the probability of same is highly likely, it seems reasonable to provide a response for these items, at least as a precaution. Please provide information for each of these items of the application.

6. **Section C, Need, Item 1 (Project Specific Criteria)**
Item 4.a – It is understood that the project does not involve documenting need for the addition of a MRI unit to the service area. However, HSDA is interested in identifying the expected impact to the existing hospital MRI service when combined with the applicant's projected utilization and when taking into account any changes to patient referrals to the hospital MRI service going forward. As such, please complete the table below.

Provider	2013	2014	2015 (estimated)	Projected Year 1	Projected Year 2
Sycamore Shoals Hosp	1,719	1,880			
Medical Care LLC				726	762
Total					
As a % of 2,880 MRI standard	60%	65.3%			

Item 7.g – Please identify any changes to the March 7, 2013 letter from the management representative of Inpatient Consultants of Tennessee that apply to this standard.

Item7.h – It is understood that radiologists of National Diagnostic Imaging located in Beechwood, Ohio will provide imaging interpretation. However, please describe arrangements planned for the medical supervision part of the standard, including any plans for on-site supervision, as necessary.

Given the provision of subspecialty teleradiology services by NDI, what safeguards will be taken to protect patient information and privacy?

7. **Section C, Need, Item 3**

The proposed 5-County Primary Service Area based on the patient caseloads of the medical group is noted (23,275 patients in 2014). Since the projected MRI utilization caseloads amounts to approximately 3% of the practice's total patients, what consideration was given to declaring a smaller PSA with fewer counties?

The applicant notes that its member physicians referred approximately 692 patients to existing MRI providers in 2014. Please provide an estimate of historical & projected MRI utilization by county of residence and compare to the total MRI utilization of residents in the PSA by completing the table below. *Note: medical equipment utilization and patient origin data for same is available from the HSDA Equipment Registry by contacting Alecia Craighead, Stat III. Alecia can be reached at 615-741-2364 or by e-mail at Alecia. L. Craighead@tn.gov*

MRI Utilization by Residents of Applicant's 5 County PSA

County of Residence	Applicant's MRI Patient Referrals - 2014	Applicant's Projected MRI Patients Year 1	Total PSA Resident MRI Procedures in 2013
Carter			
Johnson			
Sullivan			
Unicoi			
Washington			
PSA Total			

8. Section C, Need. Item 5 (Historical Utilization in PSA)

The information in the attachment from the HSDA Equipment Registry and the related analysis by the applicant in the Project Specific Standards section is noted. Please help illustrate the use of MRI by residents of the applicant's proposed 5-County Primary service Area (PSA) and Statewide by Tennessee residents by completing the table below.

Resident MRI Volumes-PSA Residents Compared to Statewide, 2011-2013

County of Residence	**Resident MRI Procedures 2011**	**Resident MRI Procedures 2012**	**Resident MRI Procedures 2013**	**% Change '11-'13**	**MRI Use Rate Per 1000 Population (2013)**
Carter					
Washington					
Sullivan					
Johnson					
Unicoi					
Subtotal-Applicant's PSA					
At all other TN provider sites					
PSA Resident procedures					
Statewide Resident Procedures					

Please complete the table below to provide a snapshot of historical MRI provider utilization and the number of patients referred for MRI by Medical Care, LLC (MCL) physician members in 2014.

Utilization of Existing MRI Providers in Applicant's PSA, 2011-2013

Provider Name	Type (PO, ODC, Hospital)	Current # units (specify if mobile)	County	Distance from Applicant (miles)	2011	2012	2013	% Change '11-'13	Patient Referrals by MCL Physicians In 2014
Provider 1									
Provider 2, etc.									
Total									

Review of HSDA Equipment Registry records revealed that the MRI utilization of Sycamore Shoals Hospital decreased by approximately 12% from 1,958 in 2011 to 1,718 MRI procedures in 2013. Of the 696 patients referred by members of the practice in 2014, how many actually used the MRI unit at Sycamore Shoals Hospital? If this project is approved, what is the likely impact to the hospital's MRI volumes?

9. Item 6 (Applicant's Projected Utilization)

The projected utilization is noted. Since the MRI service of the practice is used only by patients of Medical Care, PLLC it would help to have an appreciation of utilization grouped by primary specialties of the practice's physicians that reflects the projected volumes of the project. Please complete the table below.

Applicant's MRI Volumes by Physician Specialty

Primary Specialty	# Physicians in Practice as of May 1, 2015	# Patients Referred for MRI In 2014	Applicant's Projected MRI Procedures Year 1
Family Practice			
Internal Medicine			
Pediatrics			
OB/GYN			
Orthopedics			
General Surg			
Radiology			
Neurology			
Neurosurgery			
Podiatry			
Oncology			
Cardiology			
Urology			
Other _____			
TOTAL			

10. Section C, Economic Feasibility Item 1 (Project Costs Chart)

The MRI equipment cost should be the higher of the applicant's lease cost or estimated fair market value (FMV) of the 1.5 new Toshiba unit. In this project, it is understood that the FMV of the MRI unit would be prorated for the applicant's shared use of the unit at the hospital at a use rate of approximately 30%. However, the applicant needs to provide documentation of the current FMV of the 1.5 Tesla Toshiba from the hospital and/or equipment vendor attesting to the value of the unit and its related costs. Please note the following definition from HSDA Rule 0720-9-.01 (13)(b) for determining the FMV of the MRI unit for purposes of this project:

"The cost of major medical equipment includes all costs, expenditures, charges, fees, and assessments which are reasonably necessary to put the equipment into use for the purposes for which the equipment was intended. Such costs specifically include, but are not necessarily limited to the following: (1) maintenance agreements, covering the expected useful life of the equipment; (2) federal, state, and local taxes and other government assessments and (3) installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding."

Is the $1,597,440 MRI unit 10-year lease cost listed in Line B.4 of the Project Cost Chart consistent with the Rule? In your response, please also identify the estimated fair market value by providing documentation of the unit's current value. If any changes follow as a result of the requested comparison, please revise the amounts in the Project Cost Chart and submit as a replacement page for the application

11. Section C, Economic Feasibility, Item 4. (Historical and Projected Data Charts)

Historical Data Chart – the applicant states that Medical Care LLC saw a total of 23,275 patients and its physicians performed 75,049 patient encounters during 2014. How do these amounts relate to the 326,782 units entered in Line A (Utilization Data) of the chart? Please explain.

The applicant's Net Operating Income shows a loss of $91,759 in 2014. What factors related to the proposed MRI service are expected to help achieve a favorable margin in future years? Given the significant increase in Medical care's bad debt expense, what considerations were used to limit the bad debt expense of the proposed MRI service?

Projected Data Chart

Line D.2 – Physician Salaries and Wages – Given billing for image interpretation services by the contract radiologists of National Diagnostic Imaging, please explain the rationale for budgeting Physician Salaries for the MRI service of the practice and how the amounts were determined.

Note: if corrections are warranted as a result of these items or any additional items the applicant may wish to identify, please submit a revised Projected Data Chart numbered as page 18-R.

12. Section C., Economic Feasibility, Item 6 B.

Please also include a comparison to HSDA Equipment Registry MRI range of charges in the response (1st Quartile, Median, 3rd Quartile).

13. Section C, Economic Feasibility, Item 9

Please show the percentages by payor in Year 1 of the project by completing the table below.

MRI Service Payor Mix, Year 1

Payor Source	Year 1 Gross Revenue (as a % of total)	Average Gross Charge per MRI procedure	Year 1 Gross Revenue (as a % of total)
Medicare			
TennCare			
Managed care			
Commercial			
Self-Pay			
Other			
Total			

14. Section C, Orderly Development, Item 4

What are the full time equivalent amounts used to provide professional support for the MRI service that are factored into the projected $50,820 Physician Salary cost for Year 1 in the chart?

15. Section C, Economic Feasibility, Item 8

Review of the Historical Data Chart and Applicant's Combined Financial Statements provided for question 10 of the Economic Feasibility section revealed unfavorable Net Operating Income and Current Ratios for the 2 most recent fiscal year periods. Based on this performance, please comment on the applicant's ability to financially support the proposed MRI service should it perform below projected volumes and margins.

In accordance with Tennessee Code Annotated, §68-11-1607(c) (5), "...If an application is not deemed complete within sixty (60) days after written notification is given to the applicant by the agency staff that the application is deemed incomplete, the application shall be deemed void." **For this application the sixtieth (60th) day after written notification is July 16, 2015. If this application is not deemed complete by this date, the application will be deemed void.** Agency Rule 0720-10-.03(4) (d) (2) indicates that "Failure of the applicant to meet this deadline will result in the application being considered withdrawn and returned to the contact person. Re-submittal of the application must be accomplished in accordance with Rule 0720-10-.03 and requires an additional filing fee." Please note that supplemental information must be submitted timely for the application to be deemed complete prior to the beginning date of the

review cycle which the applicant intends to enter, even if that time is less than the sixty (60) days allowed by the statute. The supplemental information must be submitted with the enclosed affidavit, which shall be executed and notarized; please attach the notarized affidavit to the supplemental information.

If all supplemental information is not received and the application officially deemed complete prior to the beginning of the next review cycle, then consideration of the application could be delayed into a later review cycle. The review cycle for each application shall begin on the first day of the month after the application has been deemed complete by the staff of the Health Services and Development Agency.

Any communication regarding projects under consideration by the Health Services and Development Agency shall be in accordance with T.C.A. ɜ 68-11-1607(d):

(1) No communications are permitted with the members of the agency once the Letter of Intent initiating the application process is filed with the agency. Communications between agency members and agency staff shall not be prohibited. Any communication received by an agency member from a person unrelated to the applicant or party opposing the application shall be reported to the Executive Director and a written summary of such communication shall be made part of the certificate of need file.

(2) All communications between the contact person or legal counsel for the applicant and the Executive Director or agency staff after an application is deemed complete and placed in the review cycle are prohibited unless submitted in writing or confirmed in writing and made part of the certificate of need application file. Communications for the purposes of clarification of facts and issues that may arise after an application has been deemed complete and initiated by the Executive Director or agency staff are not prohibited.

Should you have any questions or require additional information, please do not hesitate to contact this office.

Sincerely,

Jeff Grimm
Health Examiner
Tennessee Health Services & Development Agency

State of Tennessee
Health Services and Development Agency
Andrew Jackson Building, 9th Floor
www.tn.gov/hsda Phone: 615-741-2364/Fax: 615-741-9884

May 28, 2015

Rachel C. Nelley, Attorney
Farris Bobango PLC
618 Church Street, Suite 300
Nashville, TN 37219

RE: Certificate of Need Application CN1505-018
Medical Care, PLLC – Initiation of Shared MRI Service for use by Patients of the Practice

Dear Ms. Neeley,
This will acknowledge our May 28, 2015 receipt of your 1st Supplemental Response pertaining to your application for a Certificate of Need to initiate MRI services for the patients of Medical Care, PLLC through a shared services and equipment agreement with Mountain States Health alliance d/b/a Sycamore Shoals Hospital to block leased time on the existing MRI unit located on the hospital's campus in Elizabethton (Carter County), Tennessee. As part of the project, the proposed MRI service will be operated as an ancillary service of Medical Care, PLLC limited to the use of its patients.

Several items were found which need clarification or additional discussion. Please review the list of questions below and address them as indicated. The questions have been keyed to the application form for your convenience. I should emphasize that an application cannot be deemed complete and the review cycle begun until all questions have been answered and furnished to this office.

Please submit responses in triplicate by 2:00 PM, Friday, May 29, 2015. If the supplemental information requested in this letter is not submitted by or before this time, then consideration of this application may be delayed into a later review cycle.

---

1. **Section B, Project Description, Item II.E.**
The cost of the applicant's 10-year lease payments was identified as $1,599,939.00 on pages 11 and 30 of the application. However, the lease cost was shown as $1,597,400.00 on line B.4 of the Project Costs Chart in the application. Accordingly, it appears that the correct amount for the 10 year lease cost that applies to this project is $1,599,939.00. Please clarify.

2. **Section C, Economic Feasibility, Item 1 (Project Cost Chart)**

The applicant provided a copy of a detailed equipment vendor quotation in the 5/28/15 supplemental response. This documentation sufficiently identifies the MRI unit's Fair Market Value (FMV) for CON application purposes as $1,830,173.00, inclusive of a 60 month service agreement cost. However, when prorated by 30% for the applicant's shared use of the hospital's MRI unit, the

FMV actually decreases to approximately $549,051.90. As such, please note that the estimated FMV should not be used in the Project Costs Chart for CON purposes since it is lower than the applicant's expected 10 year lease cost.

For the reasons described above, please provide a revised Project Cost Chart with corrected entries for the following line items of the chart:

Line B.4 (equipment lease cost)
Line D (estimated project cost)
Line E (CON filing fee)
Line F (total estimated project cost with filing fee)

In your response, please note that the new filing fee should change to $3,616.74, a difference of $5.63 from the original filing fee. Please remit the additional $5.63 filing fee amount in the form of a check or money order payable to HSDA.

In accordance with Tennessee Code Annotated, §68-11-1607(c) (5), "...If an application is not deemed complete within sixty (60) days after written notification is given to the applicant by the agency staff that the application is deemed incomplete, the application shall be deemed void." **For this application the sixtieth (60th) day after written notification is July 16, 2015. If this application is not deemed complete by this date, the application will be deemed void.** Agency Rule 0720-10-.03(4) (d) (2) indicates that "Failure of the applicant to meet this deadline will result in the application being considered withdrawn and returned to the contact person. Re-submittal of the application must be accomplished in accordance with Rule 0720-10-.03 and requires an additional filing fee." Please note that supplemental information must be submitted timely for the application to be deemed complete prior to the beginning date of the review cycle which the applicant intends to enter, even if that time is less than the sixty (60) days allowed by the statute. The supplemental information must be submitted with the enclosed affidavit, which shall be executed and notarized; please attach the notarized affidavit to the supplemental information.

If all supplemental information is not received and the application officially deemed complete prior to the beginning of the next review cycle, then consideration of the application could be delayed into a later review cycle. The review cycle for each application shall begin on the first day of the month after the application has been deemed complete by the staff of the Health Services and Development Agency.

Any communication regarding projects under consideration by the Health Services and Development Agency shall be in accordance with T.C.A. ɔ 68-11-1607(d):

(1) No communications are permitted with the members of the agency once the Letter of Intent initiating the application process is filed with the agency. Communications between agency members and agency staff shall not be prohibited. Any communication received by an agency member from a person unrelated to the applicant or party opposing the application shall be reported to the Executive Director and a written summary of such communication shall be made part of the certificate of need file.

(2) All communications between the contact person or legal counsel for the applicant and the Executive Director or agency staff after an application is deemed complete and placed in the review cycle are prohibited unless submitted in writing or confirmed in writing and made part of the certificate of

need application file. Communications for the purposes of clarification of facts and issues that may arise after an application has been deemed complete and initiated by the Executive Director or agency staff are not prohibited.

Should you have any questions or require additional information, please do not hesitate to contact this office.

Sincerely,

Jeff Grimm
Health Examiner
Tennessee Health Services & Development Agency

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF _____

NAME OF FACILITY: _____

I, _____, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

_____
Signature/Title

Sworn to and subscribed before me, a Notary Public, this the _____ day of _____, 20___, witness my hand at office in the County of _____, State of Tennessee.

_____
NOTARY PUBLIC

My commission expires _____, _____.

HF-0043

Revised 7/02

SUPPLEMENTAL - #1 COPY

Medical care, PLLC

CN1505-018

SUPPLEMENTAL

FARRIS BOBANGO, PLC

ATTORNEYS AT LAW

Nashville · Memphis

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618 CHURCH STREET, SUITE 300
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(615) 687-4231

May 28, 2015

Mr. Jeff Grimm
Health Examiner
Health Services and Development Agency
Andrew Jackson Building, Ninth Floor
502 Deaderick Street Nashville, TN 37243

RE: Certificate of Need Application CN1505-018
Medical Care, PLLC – Initiation of Shared MRI Service for use by Patients of the Practice

Dear Mr. Grimm:

This letter will serve to follow up the filing of the above-referenced certificate of need application and is submitted as a supplemental response to your e-mailed correspondence dated May 18, 2015, wherein additional information or clarification was requested.

1. **Section A, Applicant Profile, Item 1**
As the contact for the applicant may be aware, all approved Certificates of Need are site specific. Since the proposed shared MRI is located on the campus of Sycamore Shoals Hospital located at 1501 West Elk Avenue in Elizabethton, TN, please revise the address provided and submit in a replacement page 1-R.

Response – A replacement page 1-R is included as Attachment Section A., Applicant Profile, Item 1.

2. **Section A, Applicant Profile, Item 5 (Manager)**
The information for the management operating entity, including a copy of the Management Services Agreement in the attachments, is noted

Please provide a copy of the manager's current registration with the TN Secretary of State office.

Review of the Management Services Agreement for the 5 year period ending April 2015 revealed that the agreement was null and void after December 31, 2013. Given the proposal to share use of the MRI unit at Sycamore Shoals Hospital, what are the major features of the new agreement between the applicant and the manager as it relates to primary responsibilities, term and payment for services? Please clarify. As a suggestion, the applicant should provide a copy of a revised draft agreement or a letter of intent that identifies the key terms of the proposed arrangement. In your response, please also describe the manager's responsibility for providing medical and clinical supervision support for the applicant's use of the hospital's MRI unit on a block time basis.

What provisions, if any, apply to the applicant's plans to use Pine Palm Management, LLC as the manager of its proposed shared MRI service subject to prior approval by hospital? Should the manager be a party to the "Licensure Agreement" (with 12/10/14 amendment) between the hospital and applicant? If so, what are the key provisions that might apply in this regard? Please explain.

Response: Copies of the Certificate of Existence for Pine Palms Management, LLC and the current Management Services Letter of Intent are enclosed and referred to as Attachment A.5. It is not necessary for the Manager to be a party to the Licensure Agreement. The entity's role is similar to that of an individual serving in the capacity of office manager at a physician's practice. Oversight responsibilities are all non-medical and are consistent with those already being provided by Pine Palms Management to the medical practice. The practice will not be paying any additional fees to the Manager for the services related to the applicant's use of the hospital's MRI unit if the project is approved.

3. **Section A, Applicant Profile, Item 6**
Other than the "License Agreement" provided in the attachments, what additional documentation can be provided to support hospital's ownership of the premises and MRI equipment such that its authority to contract with the applicant for these items can be fully appreciated?

Response: Counsel for the hospital has assured counsel for the Applicant that all applicable agreements were signed by proper Mountain States Health Alliance or Sycamore Shoals Hospital leadership.

4. **Section B, Applicant Profile, Item 13 and Section C, Economic Feasibility, Item 6.B**

The response is noted. The applicant states that professional fees for MRI interpretation services will be billed by contracted radiologists of National Diagnostic Imaging of Beachwood, Ohio. As such, what assurances apply such that the radiologists will hold Medicare and Medicaid provider certification and will be contracted with the same TennCare MCO plans as the applicant? Please briefly discuss the arrangements planned in this regard.

Response: Medical Care, PLLC will bill globally for the MRI services and then, per its contract with NDI, pay NDI for the interpretation.

5. **Section B, Project Description, Item II.A. and Item II.E.**

Item II.A –Please briefly describe general features of the hospital and dedicated space of the MRI unit such as floor location, primary patient entrances, exits, clinical/admin support space, patient waiting, and other hospital departments on same floor closest to the MRI area.

Response: Please refer to the hospital floor plans included as Attachment Section B, Project Description, Item II.A. and Item II.E.

The applicant notes that the hospital has acquired a new MRI unit (1.5 Tesla Toshiba Titan) to replace its existing 1.5 Tesla GE Signa unit by June 1, 2015. Please briefly describe the participation of licensed architects, structural engineers or other qualified professionals in review and approval of the hospital's plans for installation of the replacement unit.

Response: The Applicant is not aware to what degree the hospital employed architects or engineers to evaluate the installation of the new MRI, but understands that the proposed space was reviewed and approved by the manufacturer and that Mountain State Health Alliance's internal facility planners/engineers reviewed and approved the plans.

Per the applicant, it appears that interim use of a mobile MRI unit may be necessary should the new fixed 1.5 Tesla Toshiba unit not be installed & operational within the June 1, 2015 timeframe desired. Please describe the mobile equipment & docking facilities available at the hospital to operate a mobile MRI should this need arise.

Response: The mobile MRI is a GE 1.5 Echospeed Plus MR System in a mobile trailer. Please refer to the Agreement between Sycamore Shoals Hospital and Shared Imaging and the floor plans included as Attachment Section B, Project Description, Item II.A. and Item II.E.

Item II.E:

1.a.1 - Fixed Site Units - Expected Useful Life - please also identify the manufacture date of the hospital's new 1.5 Tesla Toshiba MRI unit that will replace the existing GE unit in June 2015.

Response: The manufacture date of the Toshiba MRI unit is unknown to the Applicant as it is not set forth in the Agreement between Sycamore Shoals Hospital and Toshiba included as Attachment C Economic Feasibility 1. The hospital was unable to provide the Applicant with any additional information.

2.a, 2.d and 2.e – Mobile Units – as the applicant has indicated, a mobile unit at the hospital may need to be used if the hospital's replacement unit is not available. If the

probability of same is highly likely, it seems reasonable to provide a response for these items, at least as a precaution. Please provide information for each of these items of the application.

Response: It is highly unlikely that the applicant will need to use the mobile unit. With respect to item 2.1., the site to be served will be Sycamore Shoals Hospital. Please refer to the Agreement between Sycamore Shoals Hospital and Shared Imaging and the floor plans included as Attachment Section B, Project Description, Item II.A. and Item II.E. for response to items 2.d. (fair market value) and 2.e. (equipment owner).

6. **Section C, Need, Item 1 (Project Specific Criteria)**
Item 4.a – It is understood that the project does not involve documenting need for the addition of a MRI unit to the service area. However, HSDA is interested in identifying the expected impact to the existing hospital MRI service when combined with the applicant's projected utilization and when taking into account any changes to patient referrals to the hospital MRI service going forward. As such, please complete the table below.

Response: The Applicant is unable to obtain 2015 estimates from the hospital. Counsel for the hospital advises counsel for the Applicant that the hospital expects its utilization over the course of the next two (2) years to remain consistent with its 2014 utilization.

Provider	2013	2014	2015 (estimated)	Projected Year 1	Projected Year 2
Sycamore Shoals Hosp	1,719	1,880	1880	1880	1880
Medical Care LLC	960	692	242*	726	762
Total	**1719**	**1880**	**2122**	**2606**	**2642**
As a % of 2,880 MRI standard	60%	65.3%	73.7%	90.5%	91.7%

*726 ÷12 = 60.5 and 60.5 x 4 = 242 (Assumes initiation of MRI services on Aug. 27, 2015, which leaves 4 months remaining in the year 2015).

Item 7.g – Please identify any changes to the March 7, 2013 letter from the management representative of Inpatient Consultants of Tennessee that apply to this standard.

Response: There are no changes to the agreement.

Item7.h – It is understood that radiologists of National Diagnostic Imaging located in Beechwood, Ohio will provide imaging interpretation. However, please describe arrangements planned for the medical supervision part of the standard, including any plans for on-site supervision, as necessary.

Response: Sycamore Shoals Hospital has a physician on-site in the Emergency Department 24hrs a day for any required on-site emergency. The NDI radiologist are available by phone for consultation anytime MRI services are being performed. Medical Care, PLLC has physicians across the street available for any additional patient questions or consultation.

Given the provision of subspecialty teleradiology services by NDI, what safeguards will be taken to protect patient information and privacy?

Response: The images from the MRI will be sent directly to Medical Care's PAC servers and a local copy will not be maintained on the hospital PAC. NDI has a secure link to Medical Care's PAC and follow HIPAA regulation.

7. **Section C, Need, Item 3**

The proposed 5-County Primary Service Area based on the patient caseloads of the medical group is noted (23,275 patients in 2014). Since the projected MRI utilization caseloads amounts to approximately 3% of the practice's total patients, what consideration was given to declaring a smaller PSA with fewer counties?

Response: A smaller PSA with fewer counties would not have been an accurate depiction of the applicant's proposed service area.

The applicant notes that its member physicians referred approximately 692 patients to existing MRI providers in 2014. Please provide an estimate of historical & projected MRI utilization by county of residence and compare to the total MRI utilization of residents in the PSA by completing the table below. *Note: medical equipment utilization and patient origin data for same is available from the HSDA Equipment Registry by contacting Alecia Craighead, Stat III. Alecia can be reached at 615-741-2364 or by e-mail at Alecia. L. Craighead@tn.gov*

MRI Utilization by Residents of Applicant's 5 County PSA

County of Residence	Applicant's MRI Patient Referrals - 2014	Applicant's Projected MRI Patients Year 1	Total PSA Resident MRI Procedures in 2013
Carter	364	382	3175
Johnson	24	24	944
Sullivan	44	27	14795
Unicoi	15	21	1572
Washington	248	252	9338
PSA Total	**692**	**726**	**29824**

8. **Section C, Need. Item 5 (Historical Utilization in PSA)**

SUPPLEMENTAL- 1

May 28, 2015
12.25pm

The information in the attachment from the HSDA Equipment Registry and the related analysis by the applicant in the Project Specific Standards section is noted. Please help illustrate the use of MRI by residents of the applicant's proposed 5-County Primary service Area (PSA) and Statewide by Tennessee residents by completing the table below.

Response:

Resident MRI Volumes-PSA Residents Compared to Statewide, 2011-2013

County of Residence	Resident MRI Procedures 2011	Resident MRI Procedures 2012	Resident MRI Procedures 2013	% Change '11-'13	MRI Use Rate Per 1000 Population (2013)
Carter	3488	3595	3175	-7.92%	55.48
Washington	9767	10522	9338	-4.39%	72.65
Sullivan	14541	15637	14795	1.75%	93.37
Johnson	970	1029	944	-2.68%	52.08
Unicoi	2154	1622	1572	-27.02%	85.74
Subtotal-Applicant's PSA	30880	32405	29824	-3.42	78.34
At all other TN provider sites (outside PSA)	979	1070	1093	11.64%	2.87
PSA Resident procedures	**31859**	**33475**	**30917**	**-2.96%**	**40.61**
Statewide Resident Procedures	*558711*	*567263*	*561417*	*.48%*	*86.00*

Please complete the table below to provide a snapshot of historical MRI provider utilization and the number of patients referred for MRI by Medical Care, LLC (MCL) physician members in 2014.

Utilization of Existing MRI Providers in Applicant's PSA, 2011-2013

Provider Name	Type (PO, ODC, Hospital)	Current # units (specify if mobile)	County	Distance from Applicant (miles)	2011	2012	2013	% Change '11–'13	Patient Referrals by MCL Physicians In 2014
Sycamore Shoals Hospital	Hospital	1 fixed	Carter	0					
Provider 2, etc.									
Total									

Response: Please refer to the table included as Attachment 6.Section C, Need. Item 5 (Historical Utilization in PSA).

Review of HSDA Equipment Registry records revealed that the MRI utilization of Sycamore Shoals Hospital decreased by approximately 12% from 1,958 in 2011 to 1,718 MRI procedures in 2013. Of the 696 patients referred by members of the practice in 2014, how many actually used the MRI unit at Sycamore Shoals Hospital? If this project is approved, what is the likely impact to the hospital's MRI volumes?

Response: Medical Care's overall patient volumes have increased, but its MRI utilization has decreased. Medical Care's use of the Hospital's MRI will increase the overall volume, but will take some volume from surrounding counties MRI particularly Washington county.

9. **Item 6 (Applicant's Projected Utilization)**

The projected utilization is noted. Since the MRI service of the practice is used only by patients of Medical Care, PLLC it would help to have an appreciation of utilization grouped by primary specialties of the practice's physicians that reflects the projected volumes of the project. Please complete the table below.

Response:

Applicant's MRI Volumes by Physician Specialty

Primary Specialty	# Physicians in Practice as of May 1, 2015	# Patients Referred for MRI In 2014	Applicant's Projected MRI Procedures Year 1
Family Practice	26	621	651
Internal Medicine	3	59	61
Pediatrics	4	7	8
OB/GYN			
Orthopedics			
General Surg			
Radiology			
Neurology			
Neurosurgery			
Podiatry			
Oncology			
Cardiology			
Urology			
Other Gen Prc	2	5	6
TOTAL	35	692	726

10. **Section C, Economic Feasibility Item 1 (Project Costs Chart)**

The MRI equipment cost should be the higher of the applicant's lease cost or estimated fair market value (FMV) of the 1.5 new Toshiba unit. In this project, it is understood that the FMV of the MRI unit would be prorated for the applicant's shared use of the unit at the hospital at a use rate of approximately 30%. However, the applicant needs to provide documentation of the current FMV of the 1.5 Tesla Toshiba from the hospital and/or equipment vendor attesting to the value of the unit and its related costs. Please note the following definition from HSDA Rule 0720-9-.01 (13)(b) for determining the FMV of the MRI unit for purposes of this project:

"The cost of major medical equipment includes all costs, expenditures, charges, fees, and assessments which are reasonably necessary to put the equipment into use for the purposes for which the equipment was intended. Such costs specifically include, but are not necessarily limited to the following: (1) maintenance agreements, covering the expected useful life of the equipment; (2) federal, state, and local taxes and other government assessments and (3) installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding."

Is the $1,597,440 MRI unit 10-year lease cost listed in Line B.4 of the Project Cost Chart consistent with the Rule? In your response, please also identify the estimated fair market value by providing documentation of the unit's current value. If any changes follow as a result of the requested comparison, please revise the amounts in the Project Cost Chart and submit as a replacement page for the application

Response: Copies of the Quotation/Order Order Summary issued by Toshiba to Sycamore Shoals and the corresponding sixty (60) month service maintenance agreement are enclosed and are identified as Attachment C Economic Feasibility Item 1. The net price reflected for the equipment is $1,257,663.00. The amount of applicable sales tax for the equipment purchase is $0 because Mountain States Health Alliance is a tax exempt entity. The cost of the service maintenance agreement is 572,510. Thus, the total "cost" of the medical equipment is 1,830,173, 30% of which would be $549,051.90. A revised Project Cost Chart is included as Attachment Section C, Economic Feasibility Item 1.

11. Section C, Economic Feasibility, Item 4. (Historical and Projected Data Charts)

Historical Data Chart – the applicant states that Medical Care LLC saw a total of 23,275 patients and its physicians performed 75,049 patient encounters during 2014. How do these amounts relate to the 326,782 units entered in Line A (Utilization Data) of the chart? Please explain.

Response: The 326,782 units is individual CPT codes or number of line item charges. A single patient may have multiple visits within a year thus the increase in patient encounters from number of unique patients. Additionally each visit may contain multiple CPT charges (or units).

The applicant's Net Operating Income shows a loss of $91,759 in 2014. What factors related to the proposed MRI service are expected to help achieve a favorable margin in

future years? Given the significant increase in Medical care's bad debt expense, what considerations were used to limit the bad debt expense of the proposed MRI service?

Response: Medical Care, PLLC has a new office building which was totally rebuilt which has accumulated significant accelerated depreciation that has caused the net operating loss. Medical Care has had a steady positive cash flow and income prior to depreciation. The MRI will add to Medical Care's stability and profitability. The increase in the bad debt was due largely by the change in the economy and patients' financial situations which we anticipate will improve and return to lower historical averages in the future.

Projected Data Chart

Line D.2 – Physician Salaries and Wages – Given billing for image interpretation services by the contract radiologists of National Diagnostic Imaging, please explain the rationale for budgeting Physician Salaries for the MRI service of the practice and how the amounts were determined.

Response: Medical Care, PLLC bills 'globally' for the MRI services and contracts directly with NDI to pay them for the interpretation. The physician salary indicated was based on .2 of a full time radiologist physician salary of $250,000 (i.e., $50,000). Further, Medical Care will pay NDI $70 per scan. In the first year of operations, $70.00 x 726 scans equals $50,820. In the second year of operations, $70.00 x 762 equals $53,340. No corrections to the Projected Data Chart are warranted.

Note: if corrections are warranted as a result of these items or any additional items the applicant may wish to identify, please submit a revised Projected Data Chart numbered as page 18-R.

12. Section C., Economic Feasibility, Item 6 B.

Please also include a comparison to HSDA Equipment Registry MRI range of charges in the response (1st Quartile, Median, 3rd Quartile).

Response: Please refer to the table below:

County	Facility	Average Gross Charge in 2013
Washington	Appalachian Orthopedic Associates – Johnson City	$1,063.11
Sullivan	Appalachian Orthopedic Associates, PC	$1,063.90
Washington	Watauga Orthopedics, PLC	$1,450.18
Carter	Medical Care	$1,584.55 (Proposed Average Gross Charge)
Sullivan	Meadowview Outpatient Diagnostic Center	$1,696.17
	1st Quartile	$1716.87
Sullivan	Sapling Grove Outpatient Diagnostic Center	$1,737.56
Unicoi	Unicoi County Memorial Hospital	$2,299.97

Sullivan	Volunteer Parkway Imaging Center	$2,661.13
Sullivan	Holston Valley Imaging Center, LLC	$2,682.13
	Median	$2704.38
Sullivan	Holston Valley Medical Center	$2,704.38
Sullivan	Bristol Regional Medical Center	$2,751.47
Johnson	Johnson County Community Hospital	$3,558.47
Washington	Mountain States Imaging at Med Tech Parkway	$4,307.68
	3rd Quartile	$4337.02
Carter	Sycamore Shoals Hospital	$4,366.35
Sullivan	Indian Path Medical Center	$4,373.27
Washington	Franklin Woods Community Hospital	$4,408.10
Washington	Johnson City Medical Center	$4,477.30

13. Section C, Economic Feasibility, Item 9

Please show the percentages by payor in Year 1 of the project by completing the table below.

MRI Service Payor Mix, Year 1

Payor Source	Year 1 Gross Revenue (as a % of total)	Average Gross Charge per MRI procedure	Year 1 Gross Revenue (as a % of total)
Medicare	28.89%	1584.53	
TennCare	36.4%	1584.55	
Managed care	----	1584.55	
Commercial	31.53%	1584.55	
Self-Pay	2.5%	1584.55	
Other	1%	1584.55	
Total	100%	---	

14. Section C, Orderly Development, Item 4

What are the full time equivalent amounts used to provide professional support for the MRI service that are factored into the projected $50,820 Physician Salary cost for Year 1 in the chart?

Response: As stated hereinabove, the physician salary indicated was based on .2 of a full time radiologist physician salary of $250,000 (i.e., $50,000). Medical Care, PLLC bills

'globally' for the MRI services and contracts directly with NDI to pay them for the interpretation. Medical Care will pay NDI $70 per scan. In the first year of operations, $70.00 x 726 scans equals $50,820. In the second year of operations, $70.00 x 762 equals $53,340. No corrections to the Projected Data Chart are warranted.

15. **Section C, Economic Feasibility, Item 8**

Review of the Historical Data Chart and Applicant's Combined Financial Statements provided for question 10 of the Economic Feasibility section revealed unfavorable Net Operating Income and Current Ratios for the 2 most recent fiscal year periods. Based on this performance, please comment on the applicant's ability to financially support the proposed MRI service should it perform below projected volumes and margins.

Response: Medical Care has always had ample cash reserves and positive cash flow. The only reason for the negative figures is accelerated depreciation of fixed assets. The accelerated depreciation increases the equity in the fixed assets. Additionally, the practice has access to multiple lines of credit which combined exceed $1.5 million. Therefore, the applicant does not doubt its ability to financially support the proposed MRI service should it perform below projected volumes and margins.

Sincerely,

Rachel C. Nelley

Rachel C. Nelley

RCN/rwc
Encl.
cc: Steve Hopland

SUPPLEMENTAL- 1

May 28, 2015
12.25pm

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF Carter

NAME OF FACILITY: Medical Care, PLLC

I, Steven Hopkins, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

Signature/Title

Sworn to and subscribed before me, a Notary Public, this the 21st day of May, 2015, witness my hand at office in the County of Carter, State of Tennessee.

NOTARY PUBLIC

SHIRLEY M HONEYCUTT
STATE OF TENNESSEE
NOTARY PUBLIC
COUNTY OF CARTER

My commission expires 08-07, 2018.

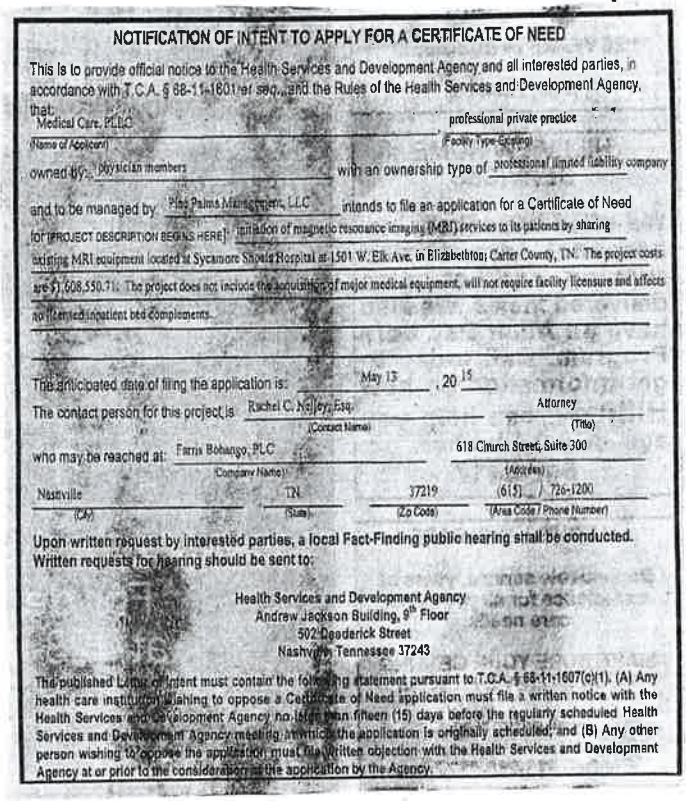
HF-0043

Revised 7/02

SUPPLEMENTAL- 1

May 28, 2015
12.25pm

STATE OF TENNESSEE
COUNTY OF CARTER



NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that:

Medical Care, PLLC (Name of Applicant) professional private practice (Facility Type (Existing))

owned by: physician members with an ownership type of professional limited liability company

and to be managed by Pilot Palms Management, LLC intends to file an application for a Certificate of Need

for [PROJECT DESCRIPTION BEGINS HERE] initiation of magnetic resonance imaging (MRI) services to its patients by sharing existing MRI equipment located at Sycamore Shoals Hospital at 1501 W. Elk Ave. in Elizabethton, Carter County, TN. The project costs are $1,608,550.71. The project does not include the acquisition of major medical equipment, will not require facility licensure and affects no licensed inpatient bed complements.

The anticipated date of filing the application is: May 15, 20 15

The contact person for this project is: Rachel C. Notley, Esq. (Contact Name) Attorney (Title)

who may be reached at: Farris Bobango, PLC (Company Name) 618 Church Street, Suite 300 (Address)

Nashville (City) TN (State) 37219 (Zip Code) (615) 726-1200 (Area Code / Phone Number)

Upon written request by interested parties, a local Fact-Finding public hearing shall be conducted. Written requests for hearing should be sent to:

Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

Judy Richardson OF SAID COUNTY BEING DULY SWORN, DEPOSETH AND SAITH THAT SHE IS THE ASSISTANT TREASURER OF THE ELIZABETHTON STAR, A NEWSPAPER PUBLISHED AT ELIZABETHTON IN THE COUNTY OF CARTER, STATE OF TENNESSEE, AND THE ORDER AND NOTICE, OF WHICH IS ANNEXED IS A TRUE COPY, WHICH WAS PUBLISHED IN SAID PAPER FOR One ~~CONSECUTIVE WEEKS~~ insertion,

COMMENCING ON THE 8th DAY OF May, 20 15
AND ENDING ON THE 8th DAY OF May, 20 15

Judy Richardson

Sworn to and subscribed before me this
the 8th day of May, 20 15

Kristina Cruz
NOTARY PUBLIC

My commission expires *June 4, 2017*

KRISTINA D. CRUZ
STATE OF TENNESSEE NOTARY PUBLIC
COUNTY OF CARTER

SUPPLEMENTAL- 1

May 28, 2015
12.25pm

Attachment Section A., Applicant Profile, Item 1.

SUPPLEMENTAL- 1

May 28, 2015
12.25pm

SECTION A:
APPLICANT PROFILE

1. ***Name of Facility, Agency, or Institution***

Medical Care, PLLC **Name**		
1501 West Elk Avenue **Street or Route**		Carter **County**
Elizabethton **City**	TN **State**	37643 **Zip Code**

2. ***Contact Person Available for Responses to Questions***

Rachel C. Nelley **Name**		Attorney **Title**	
Farris Bobango PLC **Company Name**		rnelley@farris-law.com **Email address**	
618 Church Street, Suite 300 **Street or Route**	Nashville **City**	TN **State**	37219 **Zip Code**
Attorney **Association with Owner**	615-726-1200 **Phone Number**		615-726-1776 **Fax Number**

3. ***Owner of the Facility, Agency or Institution***

Medical Care PLLC **Name**		(423) 431-0527 **Phone Number**
1500 West Elk Avenue **Street or Route**		Carter **County**
Elizabethton **City**	TN **State**	37643 **Zip Code**

4. ***Type of Ownership of Control (Check One)***

A. Sole Proprietorship
B. Partnership
C. Limited Partnership
D. Corporation (For Profit)
E. Corporation (Not-for-Profit)
F. Government (State of TN or Political Subdivision)
G. Joint Venture
H. Limited Liability Company
I. Other (Specify) PLLC

Organizational documentation is attached as Attachment A-4.

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

SUPPLEMENTAL- 1

May 28, 2015
12.25pm

Attachment A.5.

SUPPLEMENTAL- 1

STATE OF TENNESSEE
Tre Hargett, Secretary of State
Division of Business Services
William R. Snodgrass Tower
312 Rosa L. Parks AVE, 6th FL
Nashville, TN 37243-1102

May 28, 2015
12:25pm

PINE PALMS MANAGEMENT LLC
1500 W ELK AVE
ELIZABETHTON, TN 37643-2654

May 21, 2015

Request Type: Certificate of Existence/Authorization
Request #: 0163683

Issuance Date: 05/21/2015
Copies Requested: 1

Document Receipt

Receipt # : 002067200 — Filing Fee: $20.00

Payment-Check/MO - FARRIS BOBANGO PLC, NASHVILLE, TN — $20.00

Regarding: **PINE PALMS MANAGEMENT, LLC**

Filing Type: Limited Liability Company - Domestic
Formation/Qualification Date: 07/11/1997
Status: Active
Duration Term: Perpetual
Business County: CARTER COUNTY

Control # : 334299
Date Formed: 07/11/1997
Formation Locale: TENNESSEE
Inactive Date:

CERTIFICATE OF EXISTENCE

I, Tre Hargett, Secretary of State of the State of Tennessee, do hereby certify that effective as of the issuance date noted above

PINE PALMS MANAGEMENT, LLC

* is a Limited Liability Company duly formed under the law of this State with a date of incorporation and duration as given above;

* has paid all fees, taxes and penalties owed to this State (as reflected in the records of the Secretary of State and the Department of Revenue) which affect the existence/authorization of the business;

* has filed the most recent annual report required with this office;

* has appointed a registered agent and registered office in this State;

* has not filed Articles of Dissolution or Articles of Termination. A decree of judicial dissolution has not been filed.

Tre Hargett
Secretary of State

Processed By: Nichole Hambrick

Verification #: 012078321

SUPPLEMENTAL- 1

May 28, 2015
12.25pm

MANAGEMENT SERVICES LETTER OF INTENT

THIS MANAGEMENT SERVICES LETTER OF INTENT (this "agreement") is made as of May 20, 2015, by and between **Pine Palms Management, LLC** a Tennessee limited liability company (the "Manager") and **Medical Care, PLLC**, a Tennessee professional limited liability company (the "Owner"), which owns and operates physician services known as Medical Care located at 1500 West Elk Ave, Elizabethton, Tennessee and is intending to lease use of a MRI at Sycamore Shoals Hospital.

Pine Palms Management, LLC hereby offers to extend its current management services already provided to Medical Care, PLLC to include the newly initiated MRI services at Sycamore Shoals Hospital. These services will include, but not limited to;

Management Services

- Obtain and maintain the accreditation and state licensing of the Center (if the Center is accredited) and specified imaging modalities with the proper agencies and insurance companies including ACR or equivalent.
- Hiring, supervising, directing, leasing and discharging, on behalf of the Owner, all personnel performing services at the Center including the administrator of the Center (the "Administrator"), as needed. All Center personnel shall be employees of the Manager.
- Negotiating fee payment methods, in coordination with the Owner, including Medicare reimbursement, with the appropriate third party payors and state and federal agencies;
- Establishing staffing schedules, wage structures and personnel policies for all personnel;
- Determining and setting patient charges for services provided by the Center;
- Providing policies and operating procedures to all departments;
- Providing for the purchase, lease or disposition by the Owner of all supplies and equipment including information systems hardware and software used in the operation of the Center;
- Directing the day-to-day operations of the Center to insure the operations are conducted in a businesslike manner consistent with the policies adopted by Owner from time to time;
- Performing all management and non-medical oversight responsibilities for the Owner;
- Negotiating or retaining on behalf of the Owner contractual relationships for radiologist services, and other professional services as appropriate;

Accounting and Bookkeeping Services

Pine Palms Management, LLC agrees to provide or cause to be provided the following accounting and bookkeeping services for Medical Care, PLLC:

- Receipt for and deposit of all funds received from the operation of the Center and supervise the disbursement of such funds for the operating expenses of the Center.
- Maintain the books of account, including all journals and ledgers, check register and payroll records;

- Post all patient and other charges, including necessary analysis and corrections;
- Establish adequate receivables, credit and collection policies and procedures;
- Process vendors' invoices and other accounts payable;
- Prepare or contract for processing payroll checks from time sheet summaries prepared under the Manager's supervision;
- Prepare payroll and supervise preparation of the Owner's tax returns
- Prepare monthly bank reconciliations;
- Prepare monthly profit and loss statements, the format of which shall be compatible with the information systems of the Owner;
- Establish patient billing procedures;
- Conduct monthly meetings with the Owner's personnel, either telephonically or on-site as required; and
- Handle patient complaints.

The Manager shall be permitted to contract for these services with an independent accounting firm or other qualified provider

The Manager for the purpose of rendering management, administration and purchasing services and support, and all other management support needed for operation, and in the best interest, of the owner on the basis hereafter set forth, consistent with the mission of Owner and subject to the policies established by the Owner, which policies shall be consistent with applicable state and federal law.

The Manager shall perform all of the services described in the letter of intent hereof for the account of and as agent of the Owner. All such services shall be rendered using the Manager's best efforts and subject to the control of the Owner, which shall have final authority in all matters relating to the owner's operations.

The Owner will appoint the Manager its attorney-in-fact with full power on its behalf and in its name, or in the name of the Center, to enter into contracts relating to the affairs of the Center; provided, however, the Manager shall not incur any obligation for repairs, equipment, additions or betterments if to do so would exceed budgeted expenditure levels (whether capital or operating) without first requesting the consent of Owner. In the event that Owner does not respond in writing to Manager's expenditure request within five (5) days of receipt thereof, then such expenditure shall be deemed approved by Owner.

The proposed term of the Agreement shall commence as of the date set forth in the preamble of the Agreement and shall continue for a term of five (5) years The Agreement shall automatically renew for additional successive terms of one (1) year each unless one party gives the other party sixty (60) days prior written notice of termination before the expiration of the then current term.

The Owner shall have the right to terminate the agreement upon the Manager's material breach of the agreement. In the event termination is for an alleged material breach by the Manager, such notice shall describe in detail the basis upon which the Owner believes such termination is justified. Upon receipt of such notice, the Manager shall have ninety (90) days (or thirty (30) days in the event that the Manager's breach materially and adversely affects patient safety and quality of care) during which to attempt to cure any alleged default under the agreement, and upon such cure being effected, the Owner's rights to terminate shall cease and the agreement will continue in full force and effect. Furthermore, if the Manager has diligently attempted to effect such a cure within such cure period but cannot complete such cure because of the failure of a third party (such as a governmental

agency) to act within such period, then the Manager shall have a reasonable time beyond such cure period to complete its cure of the alleged basis for the Owner's election to terminate.

The Manager shall have the right to terminate the Agreement upon the Owner's material breach of the agreement. In the event termination is for an alleged material breach by the Owner, such notice shall describe in detail the basis upon which the Manager believes such termination is justified. Upon receipt of such notice, the Owner shall have ninety (90) days (or thirty (30) days in the event that the Owner's breach materially and adversely affects patient safety and quality of care) during which to attempt to cure any alleged default under the agreement, and upon such cure being effected, the Manager's rights to terminate shall cease and the agreement will continue in full force and effect. Furthermore, if the Owner has diligently attempted to effect such a cure within such cure period but cannot complete such cure because of the failure of a third party (such as a governmental agency) to act within such period, then the Owner shall have a reasonable time beyond such cure period to complete its cure of the alleged basis for the Manager's election to terminate. Notwithstanding the foregoing, Manager shall have the right to suspend the provision of services under the agreement in the event that Owner fails to pay any of the compensation payable pursuant to Article IV as and when due.

If either party shall appoint or consent to the appointment of a receiver, trustee or liquidator of such party or of all or a substantial part of its assets, file a voluntary petition in bankruptcy, make a general assignment for the benefit of creditors, file a petition or an answer seeking reorganization or arrangements with creditors or to take advantage of any insolvency law, or if an order, judgment or decree shall be entered by any court of competent jurisdiction, on the application of a creditor, adjudicating such party bankrupt or insolvent, and such order, judgment or decree shall continue unstayed and in effect for any period of ninety (90) days, then, in case of any such event, the term of the agreement shall terminate, at the option of the non-defaulting party, upon written notice to the other party.

In addition to the foregoing, after the first anniversary of the effective date of the agreement, either party may terminate the agreement, without cause, upon not less than ninety (90) days prior written notice.

All notices permitted or required by the agreement shall be deemed given when in writing and delivered personally via overnight courier or deposited in the United States mail, postage prepaid, return receipt requested, addressed to the other party at the address set forth below or such other address as the party may designate in writing:

To the Owner:	Medical Car, PLLC 1500 West Elk Ave Elizabethton, Tennessee 37643
To the Manager:	Pine Palms Management, LLC 401 East Main Street Johnson City, Tennessee 37601

Owner will agree to indemnify and hold harmless Manager, its affiliates and shareholders and their respective shareholders, directors, officers, employees and agents (collectively, a "Manager Indemnified Party") from and against any and all losses, claims, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses related to the defense of any claims) (a "Loss"), which may be asserted against any of the Manager Indemnified Parties or for which they may now or hereafter become subject arising in connection with the activities of the Center, including without limitation matters relating to: (i) alleged or actual failure by the governing body, board of directors and/or similar body of Owner to perform any of its duties under the agreement; (ii) any pending or threatened medical malpractice or other tort claims asserted against Manager relating to the Center; (iii) any action against Manager brought by any of the Center's current or former employees or medical staff members; (iv) any act or omission by any Center employee, medical staff member or other personnel; and (v) any violation of any requirement applicable to the Center under any federal, state or local environmental, hazardous waste or similar law or regulation; provided that such Loss (a) has not been caused by the gross negligence, willful misconduct or illegal conduct of Manager or the Manager Indemnified Party seeking indemnification pursuant to the agreement or (b) is not related to a breach by Manager or any of its contractual obligations to Owner arising under the agreement.

Manager agrees to indemnify and hold harmless the Owner and its members, partners, or shareholders (as appropriate), its directors or governors (as appropriate), and its officers, employees and agents (collectively, an "Owner Indemnified Party") from and against all Loss which may be asserted against any Owner Indemnified Party as a result of the gross negligence, willful misconduct or illegal conduct of Manager or a material breach of Manager's obligations under the agreement in connection with the performance by Manager of its duties hereunder; provided that such Loss has not been caused by the gross negligence, willful misconduct or illegal conduct of the Owner or the Owner Indemnified Party seeking indemnification pursuant to the agreement.

The agreement shall be construed to be in accordance with any and all federal and state laws, including laws relating to Medicare, TennCare, Medicaid, and other third party payers. In the event there is a change in such laws, whether by statute, regulation, agency or judicial decision, that has any material effect on any term of the agreement, or in the event that counsel to one party determines that any term of the agreement poses a risk of violating such laws, then the applicable term(s) of the agreement shall be subject to renegotiation and either party may request renegotiation of the affected term or terms of the agreement, upon written notice to the other party, to remedy such condition. In the interim, the parties shall perform their obligations hereunder in full compliance with applicable law.

IN WITNESS WHEREOF, the parties have executed this Letter of Intent on the date first above written.

MANAGER:

PINE PALMS MANGEMENT, LLC

By: _____

Title: CEO - Chief Manager

OWNER:

MEDICAL CARE, PLLC

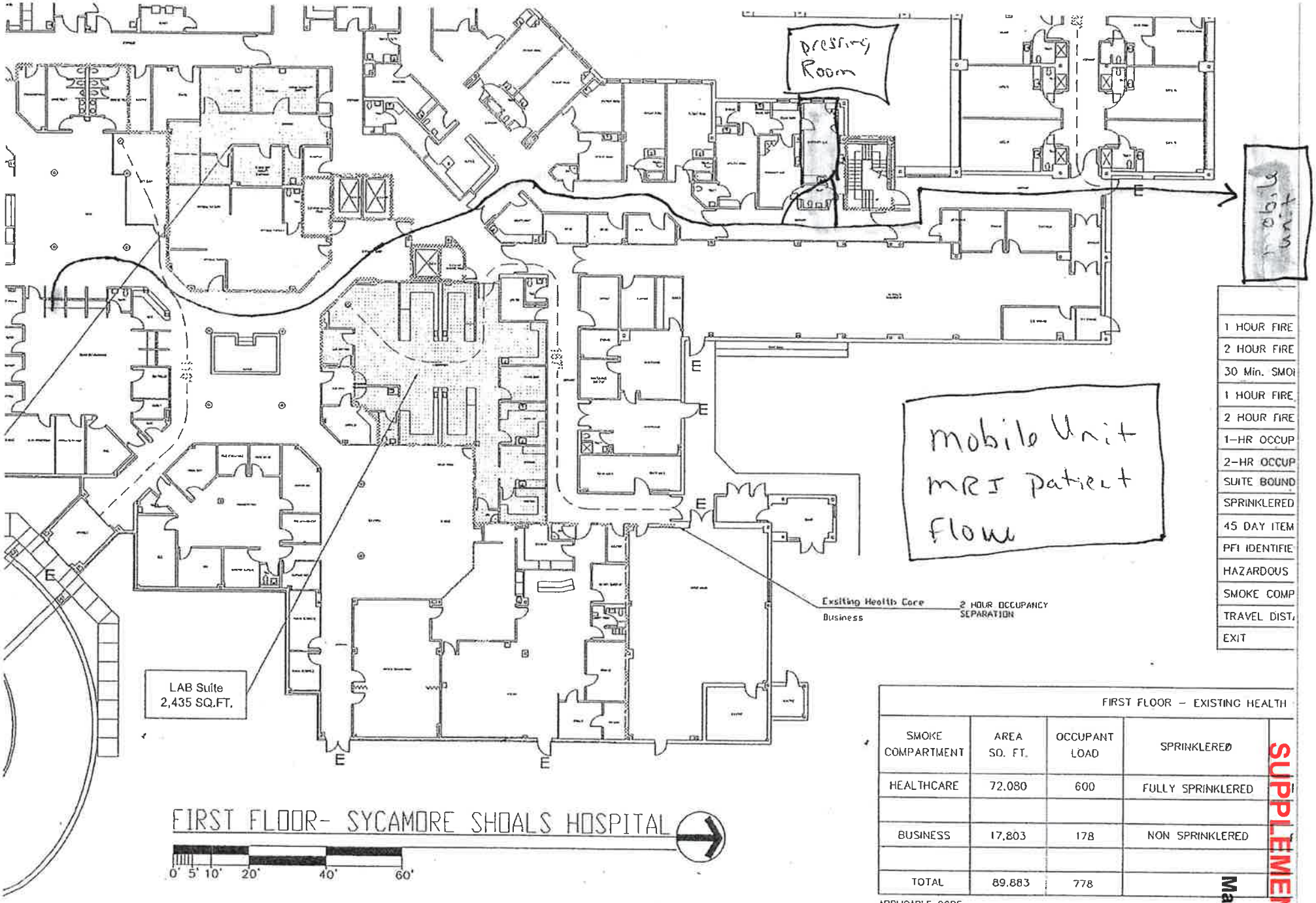
By: _____

Title: _____

SUPPLEMENTAL- 1

May 28, 2015
12.25pm

Attachment Section B, Project Description, Item II.A. and Item II.E.

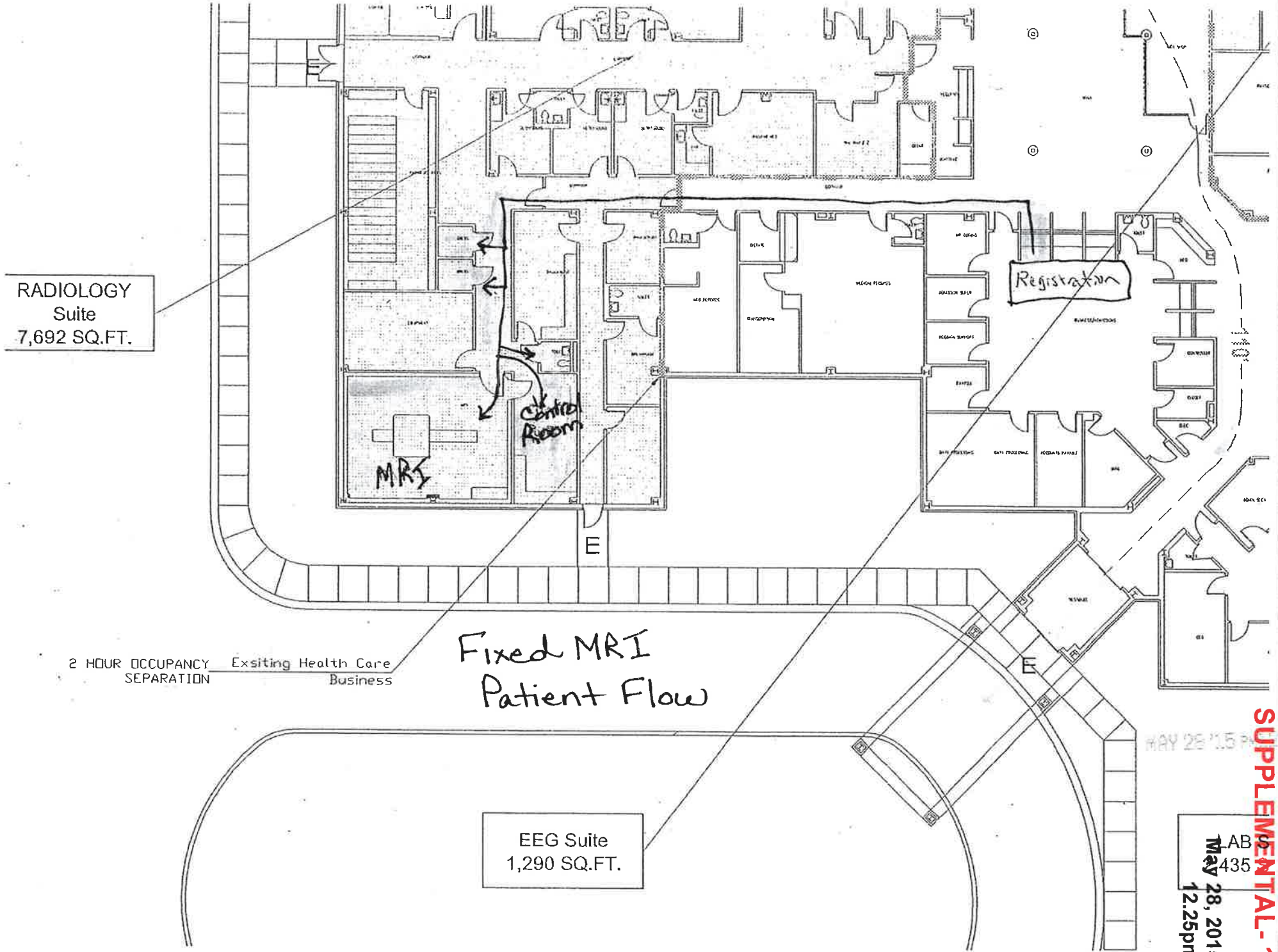


1 HOUR FIRE
2 HOUR FIRE
30 Min. SMOI
1 HOUR FIRE
2 HOUR FIRE
1-HR OCCUP
2-HR OCCUP
SUITE BOUND
SPRINKLERED
45 DAY ITEM
PFI IDENTIFIE
HAZARDOUS
SMOKE COMP
TRAVEL DIST.
EXIT

FIRST FLOOR – EXISTING HEALTH			
SMOKE COMPARTMENT	AREA SQ. FT.	OCCUPANT LOAD	SPRINKLERED
HEALTHCARE	72,080	600	FULLY SPRINKLERED
BUSINESS	17,803	178	NON SPRINKLERED
TOTAL	89,883	778	

APPLICABLE CODE:
NFPA 101,"LIFE SAFETY CODE, 2000 EDITION

SUPPLEMENTAL-1
May 28, 2015
12:25pm



SUPPLEMENTAL- 1

SHAREDIMAGING
CHANGE. SOLVED.

May 28, 2015
12.25pm

QUOTATION

EXHIBIT A

Quote #:	AAAQ1183-01
Date:	1/21/2015
Expires:	1/31/2015

Prepared For: Chuck Yunker
Mountain States Health Alliance
d/b/a Sycamore Shoals Hospital
1501 West Elk Avenue
Elizabethton, TN 37643
United States

Submitted By: David Stachowiak
630-483-3980

Selection	System	Description	Term	Price Per Week
	Interim MR System In a Mobile Trailer	GE 1.5 Echospeed Plus MR System	13 Weeks	$5,000.00
	Interim MR System In a Mobile Trailer	GE 1.5 Echospeed Plus MR System	Weekly Extensions	$4,750.00

*All Equipment is Subject to Availability

Shared Imaging Provides

1. Equipment - GE 1.5 Echospeed Plus MR System, in a Mobile Trailer, with a Power Injector.
2. Service and Preventive Maintenance Coverage - including all parts, labor (8:00AM - 9:00PM, M-F) and cryogens. Overtime coverage is the responsibility of Client.
3. Transportation to and from customer site.
4. Set-up of Equipment at customer prepared site.
5. Check out of the MR by the manufacturer's service engineer.
6. Comprehensive Insurance.

Client Provides

1. Prepared site (with power), preferably 2-3 days in advance of requested start date.
2. Technologist.
3. PACs.
4. Supplies - contrast media, film, gowns, etc.
5. An Initial Payment in the amount of $20,000 (includes Transportation charges and Initial Term charges of 4 weeks) is required before delivery will commence on the mobile system. Payments for all extensions are due at the beginning of that extension period.
6. Copy of Sales Tax Exemption Certificate if you are tax exempt or the name of your county along with the sales tax rate to be charged if you are not. Also your deposit should include sales tax if you are taxable.

Approval/Initials:
Approval/Initials:

SUPPLEMENTAL- 1

May 28, 2015
12.25pm

AGREEMENT

This AGREEMENT is dated this 2nd day of February, 2015, by and between _Mountain States Health Alliance d/b/a Sycamore Shoals Hospital (please print formal legal name) organized in the State of Tennessee Tax ID# 780184123 (Tax ID#) (hereafter "CLIENT") located at 1501 West Elk Avenue, Elizabethton, Tennessee 37643 and Shared Imaging, LLC (hereafter "SHARED"), located at 801 Phoenix Lake Avenue, Streamwood, Illinois 60107.

WHEREAS SHARED will provide equipment in the field of diagnostic imaging: and

WHEREAS CLIENT wishes to make diagnostic imaging equipment available to its patients: and

WHEREAS it is the intent of this AGREEMENT that diagnostic imaging equipment (hereafter the Equipment, as more specifically outlined in Exhibit "A" attached hereto and incorporated herein) be placed at CLIENT's location.

NOW THEREFORE, in consideration of the mutual covenants and promises herein set forth, the parties hereto do hereby agree as follows:

1. SHARED REQUIREMENTS
   a. SHARED hereby provides to CLIENT and CLIENT hereby accepts from SHARED the Equipment to be supplied by SHARED pursuant to this AGREEMENT, which shall include, but not be limited to, Equipment set forth in Exhibit "A", attached hereto and incorporated herein.
   b. SHARED will arrange to provide site planning assistance to CLIENT in coordinating layouts of Equipment's environment and liaison with CLIENT's architect or consultant for planning the operating environment for Equipment.
   c. SHARED will provide and pay for shipping and installation.
   d. SHARED as owner of Equipment shall bear full financial responsibility of insurance, if any, to cover any loss of said Equipment, except for the loss of use and income to CLIENT.
   e. During the term of this AGREEMENT, SHARED, or through its authorized agent, shall provide all necessary service and preventive as further described in Exhibit A, in order to keep the Equipment in good operating order. Overtime charges are the responsibility of CLIENT.
   f. SHARED may provide applications training as further described in Exhibit A. Thereafter, additional applications' training is available for an additional charge.
   g. SHARED will provide the initial connection to the CLIENT's network for the purpose of sending DICOM images to the CLIENT's PACs, Teleradiology system or similar networked modality. Any change to the initial connection can be provided for at an additional charge.
   h. SHARED agrees to carry general liability insurance during the term of this AGREEMENT, covering SHARED's actions at CLIENT's location in the minimum amounts of One Million Dollars ($1,000,000.00) per occurrence and Three Million Dollars ($3,000,000.00) in aggregate. SHARED agrees to provide CLIENT with a Certificate of Insurance at the time of the initiation of service and on an annual basis, and CLIENT will be notified on renewal or change. CLIENT shall be responsible for any and all other or additional insurance which CLIENT requires and be responsible for all acts or omissions of its medical staff, employees or other outside contractors.

2. TERM
   Equipment will be provided for an Initial Period of _THIRTEEN (13) WEEKS_ (hereafter "Initial Period") following the day the Equipment is installed and ready for first clinical use (hereinafter "Commencement Date").

   a. This Agreement shall become effective at the time the AGREEMENT has been signed by both parties and the Initial Period of the AGREEMENT shall commence on the Commencement Date.
   b. During the life of this contract, CLIENT will not duplicate the diagnostic imaging modality provided by the Equipment nor expand, contract for, or in any way initiate another similar diagnostic imaging modality under the terms of this AGREEMENT without prior consent in writing from SHARED.
   c. Either party shall have the right to terminate this Agreement in its entirety without cause by providing at least thirty (30) days' prior notice, without any liability to the other party for such termination.

3. PRICE SCHEDULE
   Price Schedule is as shown in Exhibit A.
   a SHARED shall invoice CLIENT at the beginning of each month. CLIENT shall pay to SHARED for said invoices within thirty (30) days of receipt of invoice. CLIENT shall pay to SHARED interest on such overdue payment, from the due date of such payment to the date of payment thereof, at a rate equal to the lesser of fifteen percent (15%) per annum and the maximum rate permitted by law. If payment terms are mentioned in Exhibit A, then Exhibit A shall prevail.
   b. CLIENT agrees to pay and discharge when due all license fees, assessments, sales, use, personal property and other tax or taxes now or hereafter imposed by any state, federal or local government or other taxing authority with respect to the AGREEMENT, Equipment or the purchase, use, lease, operating control or value thereof, but excluding taxes based upon SHARED's net income.
   c. In consideration of the performance by SHARED of its obligations pursuant to this AGREEMENT, CLIENT agrees to pay SHARED at rates initially established as set forth in Exhibit "A" attached hereto and incorporated herein, and further, that the rates shall be adjusted annually effective on the first day of the month following the month in which the Start Date occurs. The adjustment will be computed by adjusting the base rates by the increase in the Bureau of Labor Statistics' Consumer Price Index, Medical care services (Table 1.) from the level of said Index most currently available at the time of adjustment.

4. CLIENT REQUIREMENTS
   a. CLIENT will provide diagnostic imaging services for its inpatients and outpatients by way of this service from SHARED and will make best efforts to ensure the diagnostic imaging Equipment is utilized for this purpose.
   b. Preparation of Equipment's site to manufacturer's specifications and any required permits, licenses, regulatory approvals (including Certificate of Need the "CON"), are the responsibility of CLIENT.
   c. During the Term of this AGREEMENT, CLIENT agrees to provide SHARED with adequate space within CLIENT's premises to accommodate Equipment and furnishings required to this AGREEMENT. CLIENT agrees to provide the housekeeping and all utilities necessary for such space and Equipment.
   d. CLIENT agrees that it shall execute diligence in providing for the security and protection of the diagnostic imaging Equipment.
   e. CLIENT shall promptly report to SHARED any servicing problems which are not adequately handled by the service organization hired by SHARED.
   f. In the event that Equipment or any part thereof is lost, destroyed or damaged (except for normal wear), due to negligence on the part of the CLIENT, CLIENT will promptly give SHARED notice of such loss or damage. CLIENT will take immediate action at SHARED's direction to repair, restore or replace Equipment or any part thereof at CLIENT's sole cost.

AGREEMENT continued:

g. CLIENT shall permit any person designated by SHARED at SHARED's expense, to visit and inspect Equipment at such reasonable times and places and as often as SHARED may reasonably request.

h. CLIENT shall provide film, contrast material, recording media, and other supplies as appropriate for the Equipment.

i. Under ideal conditions the facility input power for the proposed system should be checked using a power line disturbance monitor for average line voltage, surge, sags, impulses and frequency. The possibility of power sags or "brown outs" must be taken into consideration. Any existing power problems with large consumers (x-ray, computers, etc.) must be reviewed as they may affect the performance of the System. Results of line analysis should be assessed with your SHARED representative to determine if customer provided line conditioning is needed. If power conditioning is required, CLIENT will bear associated costs.

5. DISCLAIMER OF WARRANTIES

a. SHARED SUPPLIES EQUIPMENT "AS IS" AND IS NOT ACTING AS THE MANUFACTURER OF EQUIPMENT, THE MANUFACTURER'S AGENT OR THE SELLER'S AGENT AND MAKES NO WARRANTY OR REPRESENTATION, EITHER EXPRESSED OR IMPLIED, AS TO THE MERCHANTABILITY, FITNESS, DESIGN OR CONDITION OF, OR AS TO THE QUALITY OR CAPACITY OR, THE MATERIAL OR WORKMANSHIP IN EQUIPMENT, OR ANY WARRANTY THAT THE EQUIPMENT WILL SATISFY THE REQUIREMENTS OF ANY LAW, RULE, SPECIFICATION OR CONTRACT WHICH PROVIDES FOR SPECIFIC EQUIPMENT.

It is being agreed that all such risks, between SHARED and CLIENT are to be borne by CLIENT at its sole risk and expense. Under no circumstance is SHARED responsible for direct, indirect or consequential damages under this AGREEMENT.

6. COMPLIANCE WITH APPLICABLE LAW

a. CLIENT shall use Equipment solely in the conduct of its business, in a manner and for the use contemplated by the manufacturer thereof, and in compliance with all laws, rules and regulations of every governmental authority having jurisdiction over Equipment and the business or operations of CLIENT.

7. OWNERSHIP

a. Equipment will be kept by CLIENT in its sole possession and control, will at all times be located on the premises stated herein, and will not be removed without prior written consent of SHARED. CLIENT will not make or permit to be made any alteration or addition to Equipment without the prior written consent of SHARED. CLIENT will keep and maintain the Equipment free and clear of all liens, charges and encumbrances. CLIENT may not assign this AGREEMENT or any of CLIENT's rights hereunder or sublease Equipment or otherwise allow others to use Equipment without the prior written consent of SHARED. Equipment as set forth in Exhibit "A" and any subsequent alteration, changes, or upgrades is the personal property of SHARED and may be removed by SHARED at any time after the Termination Date. CLIENT shall permit SHARED to affix to Equipment and each unit or element thereof, appropriate tags, decals or plates indicating the ownership of such Equipment by SHARED, and CLIENT shall not cause or permit any such tags, decals or plates to be removed, defaced or covered in any way.

8. DEFAULT OF CLIENT & REMEDIES

a. The occurrence of any of the following shall constitute an Event of Default hereunder:

i. CLIENT shall fail for a period of ten (10) days to pay all or any portion of any payment due hereunder.

ii. CLIENT shall commit an act of bankruptcy within meaning of the Federal Bankruptcy Act.

iii. CLIENT shall breach any of its covenants herein, other than i and ii above, and such breach shall continue for ten (10) days after notice from SHARED.

b. If an Event of Default hereunder, shall occur, SHARED may without liability terminate this AGREEMENT and CLIENT's rights hereunder, enter CLIENT's premises and repossess Equipment from CLIENT and collect all monies due under this AGREEMENT.

c. All of SHARED's remedies hereunder shall be cumulative and not exclusive of one another or any other right or remedy to which SHARED is entitled at law, inequity, or otherwise.

d. After an Event of Default occurs or after termination, CLIENT does hereby grant to SHARED a license to enter upon the Location without any order of court and remove the Equipment without obligation to repair or restore the Location.

9. EXTENSION

a. In the event CLIENT does not notify SHARED fifteen (15) days in advance, of AGREEMENT expiration in writing of its intent to return the Equipment or of its intent to negotiate a mutually acceptable extension or renewal, or purchase of the equipment in writing, the AGREEMENT will be extended at the price schedule as described on Exhibit A. Upon termination of the AGREEMENT, said equipment shall be returned to SHARED in as good condition as received less normal wear, tear and depreciation.

10. ASSIGNMENT

a. All rights, privileges and indemnities of SHARED hereunder may be assigned, pledged, transferred, or otherwise disposed of, either in whole or in part, without consent of CLIENT and SHARED's assignee or secured party may reassign said interest subject to CLIENT's rights hereunder), without consent of CLIENT. Without SHARED's prior written consent, CLIENT shall not:

i. Assign, Transfer, pledge, hypothecate or otherwise dispose of this AGREEMENT, Equipment, or any interest herein, or

ii. Sublet or lend Equipment.

Subject to the forgoing, the AGREEMENT inures to the benefit of and is binding upon the successors and assigns of the parties hereto.

b. In the event of an assignment:

i. CLIENT hereby acknowledges the existence of any Security Agreement, including the provision assigning, after an event of default, the payments from CLIENT to SHARED's assignee.

ii. SHARED agrees with CLIENT that so long as CLIENT is not in default of any of the terms, covenants or conditions on the part of CLIENT to be performed or observed under the AGREEMENT beyond any period given CLIENT to cure such defaults and so long as CLIENT is in compliance with the terms and provisions of this AGREEMENT, CLIENT's possession and use of Equipment shall not be disturbed, terminated, diminished, altered or interfered with by SHARED or SHARED's assignee, and the rights and privileges granted CLIENT under the AGREEMENT or any extensions or renewals thereof effected in accordance with the options provided in the AGREEMENT, shall not be disturbed, terminated, diminished, altered or interfered with by SHARED or SHARED's assignee.

iii. SHARED hereby authorizes and directs CLIENT, upon receipt of notice from SHARED that an event of default exists under a Security Agreement, to attorn to and recognize SHARED's assignee as having all of the rights of SHARED under all of the terms of the AGREEMENT and to timely pay and perform to SHARED's assignee all of the obligations to be paid and performed by CLIENT under the AGREEMENT for the balance of the term with the same force and effect as though SHARED's assignee were under the AGREEMENT.

c. If at any time this AGREEMENT, and the transactions evidenced hereby, shall be construed to create a security interest, then this AGREEMENT shall be deemed to be a security agreement, SHARED shall be the secured party, and CLIENT the debtor. In such situation, CLIENT hereby grants to SHARED a security interest in, and authorizes SHARED to file (in any necessary jurisdiction) UCC financing statements describing, the Equipment, together with all replacement parts, additions, repairs, accessions, and accessories incorporated therein and/or affixed thereto, and all proceeds thereof (the "Collateral"); provided, however, that nothing herein, nor the filing of any financing statement, shall constitute an acknowledgment that this transaction creates a security interest.

d. If requested, CLIENT agrees to:
   i. sign an acknowledgement of an assignment;
   ii. provide landlord waivers and/or mortgagee waivers;
   iii. sign or provide any other reasonable documents required by SHARED to perfect security interest.

e. CLIENT agrees to the provision of audited and/or interim financial statements and statistical information upon request of and to SHARED as requested during the term of AGREEMENT.

11. BINDING AGREEMENT

a. This AGREEMENT and all Exhibits and Amendments hereto contains the entire AGREEMENT between SHARED and CLIENT with respect to the subject matter herein and supersedes any prior understandings or agreements between the parties or their agents with respect thereto.

b. This AGREEMENT may be altered or amended only by signed written agreement between the parties.

c. The waiver by a party or a breach of any provision of this AGREEMENT shall not operate or be considered as a waiver of any subsequent breach.

d. If any part of this AGREEMENT is or shall become legally invalid for any reason, the same shall be deemed to be severable for the remainder thereof; any such invalidity shall in no way affect the validity of this AGREEMENT as a whole or any other part or portion thereof. The AGREEMENT shall be binding upon and inure to the parties, hereto, their Successors and Assigns.

e. Any notice shall be in writing and shall be addressed to each party at the location designated on the first page of this AGREEMENT, or alternatively as designated by notice.

12. CAUSES FOR EXCLUSION/SEPARATE CHARGES

This AGREEMENT specifically excludes labor, parts and expenses necessary to repair equipment:

a. damaged by fire, accident, misuse, abuse, negligence, improper application or altercation by the CLIENT's failure to operate the equipment in accordance with the instructions as described in the manufacturer's operator's manual or to maintain the required operating environment;

b. defective due to unauthorized attempts by the CLIENT or any third party to repair, relocate, maintain, service or modify the equipment; or

c. which failed due to causes from non-SHARED supplied or authorized equipment, parts or software.

If SHARED or SHARED's authorized representative is called upon to service or repair equipment that falls under this Section, a separate invoice will be issued for the subsequent labor, parts and expenses incurred.

13. FORCE MAJEURE

SHARED will not be liable to CLIENT for any failure to fulfill its obligations under this AGREEMENT due to causes beyond its reasonable control and without its negligence including, but not limited to, governmental laws and regulations, acts of God or the public, war or other violence, civil commotion, blockades, embargoes, calamities, floods, fires, earthquakes, explosions, storms, strikes, lockouts, work stoppages, unavailability of raw materials or power. In addition, in the event of any determination pursuant to the provisions of a collective bargaining agreement between the CLIENT and any labor union representing the CLIENT's employees preventing or hindering the performance of any of the obligations of SHARED under this AGREEMENT, then SHARED shall be excused from the performance of such obligations unless the CLIENT makes all required arrangements with the trade union, or unions, to permit SHARED to perform the work.

14. RELATIONSHIP

In the performance of its obligations pursuant to this AGREEMENT, SHARED shall be for all purposes, an independent contractor and there shall be no other relationship between the parties in connection with such obligations.

15. EXCLUDED PROVIDER

SHARED hereby represents and warrants that SHARED and its employees, contractors, subcontractors or agents are not and at no time have been excluded from participation in any federally funded health care program, including but not limited to Medicare and Medicaid. SHARED hereby agrees to notify CLIENT immediately after SHARED becomes actually aware of any threatened, proposed, or actual exclusions of SHARED from any federally funded health care program, including but not limited to Medicare and Medicaid. In the event that SHARED is excluded from participation in any federally funded health care program during the term of this AGREEMENT, or after the effective date of this AGREEMENT it is determined that SHARED is in breach of this Section, this AGREEMENT shall, as of the effective date of such exclusion or breach, automatically terminate. SHARED shall indemnify and hold harmless CLIENT against all actions, claims, demands and liabilities, and against all loss, damage, costs and expenses, including reasonable attorneys' fees, arising directly or indirectly, out of any violation of the Excluded Providers Section of this AGREEMENT by SHARED or due to the exclusion of SHARED from a federally funded health care program, including but not limited to Medicare and Medicaid, or out of an actual or alleged injury to a person or to property as a result of the negligent or intentional act or omission of SHARED or any of SHARED employees, contractors, subcontractors or agents in connection with SHARED obligations under this AGREEMENT, except to the extent any such loss, damage, costs and expenses were caused by the negligent or intentional act or omission of CLIENT, its officers, employees, or agents.

16. ACCESS TO RECORDS:

The following clause is included herein because of possible application of Section 1861 (v)(1)(I) of the Social Security Act; if that Section should be found inapplicable to this AGREEMENT, then this clause shall be deemed not to be part of this AGREEMENT and shall be null and void.

1. Until the expiration of four (4) years after the furnishing of services pursuant to this contract, SHARED shall make available upon written request of the Secretary of the Department of Health and Human Services or the U.S. Comptroller General or any of their duly authorized representatives, this contract, and books, documents, and records of SHARED that are necessary to verify the nature and extent of costs incurred by the Facility under this AGREEMENT.

2. If SHARED carries out any of the duties of this contract with a value of $10,000 or more over a twelve (12) month period through a subcontract with a related organization, such contract must contain a clause to the effect that until the expiration of five (5) years after the furnishing of services under the subcontract, the related organization shall make available upon written request of the Secretary of the Department of Health and Human Services, the U.S. Comptroller General or any of their representatives, this contract, and books, documents, and records of SHARED that are necessary to verify the nature of extent of costs incurred by the Facility under this subcontract.

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AGREEMENT continued:

17. LAW AND JURISDICTION
This AGREEMENT has been negotiated and executed and shall be performed, in whole or in part, in the State of Tennessee. Accordingly, the parties agree and covenant as follows:
a. This AGREEMENT shall be constructed under the applicable laws of the State of Tennessee;
b. Exclusive jurisdiction and venue over any disputes arising under this AGREEMENT shall rest in the Circuit Court of Tennessee or, if federal jurisdiction is otherwise appropriate, in the United States District Court for Tennessee. The parties hereby waive any objection to the jurisdiction or venue of the above forums, including but not limited to any objective premised on the doctrine of *forum non conveniens*.

18. ADDITIONAL TERMS:
This Agreement is subject to the Mountain States Health Alliance standard vendor contract terms and conditions as defined in the Amendment, which is attached hereto and made part of this Agreement.

MOUNTAIN STATES HEALTH ALLIANCE D/B/A SYCAMORE SHOALS HOSPITAL
(please print formal legal name)

TAX ID#_780184123

BY: Timothy S. Belisle (Signature)
(Print)

TITLE: VP + General Counsel DATE: 2/2/15

APPROVED BY MSHA CORPORATE CONTRACTS
MSHA LEGAL DEPARTMENT APPROVAL NOT REQUIRED

Agreement is accepted by SHARED and valid only if signed by an officer of SHARED. Acceptance is dependent upon the analysis of the financial and statistical information as requested by SHARED.

SHARED IMAGING, LLC (Officer):

BY: Sam Cawley (Signature)
(Print)

TITLE: CFO DATE: 2/3/15

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TERMS AND CONDITIONS
AMENDMENT TO SHARED IMAGING AGREEMENT

This Terms and Conditions Amendment to Shared Imaging Agreement (this "Amendment"), is made effective as of the 2nd day of February, 2015 (the "Effective Date") by and between Mountain States Health Alliance ("MSHA") and Shared Imaging, LLC (hereinafter "Vendor").

MSHA. "MSHA" refers to the Mountain States Health Alliance affiliate with whom the Vendor will contract (the "Agreement") for the Vendor to provide goods or perform services. An affiliate shall mean an entity controlled by, controlling, or under common ownership with MSHA. If an MSHA Affiliate is a party to this Agreement and in the event that MSHA's ownership interest or control in any Affiliate is divested, then this Agreement shall be terminated as to such Affiliate only. MSHA shall provide timely written notice of the effective date of such divestiture to Vendor. Upon the effective date of the divestiture, all rights and obligations of the parties under this Agreement as pertaining to such Affiliate shall be terminated.

WHEREAS, MSHA and Vendor entered into Shared Imaging Agreement dated February 2, 2015 (the "Agreement"); and

WHEREAS, MSHA and Vendor desire to amend the Agreement as provided herein.

NOW, THEREFORE, in consideration of the mutual covenants herein stated and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged and agreed, the parties hereby amend the Agreement as follows:

A. **Amendments.** The following terms and conditions are hereby added to the Agreement and incorporated therein:

1. **Vendor Certification and Conduct.** All Vendor employees, agents or representatives (collectively "personnel") providing services hereunder shall complete MSHA's Vendor Certification Program, orientation and badging process. While performing services in MSHA's facility, Vendor personnel shall wear appropriate Vendor identification badges and shall not hold themselves out as employees or personnel of MSHA. While present on MSHA premises or accessing MSHA Information Systems, Vendor personnel will be subject to the policies and procedures of MSHA. MSHA may exercise its discretion and remove or bar any Vendor personnel who poses an immediate risk of harm to self, others, or property or who is deemed to be conducting oneself contradictory to the MSHA's mission.

2. **Debarment and Suspension.** Vendor hereby certifies that neither it nor any of its personnel providing services on behalf of MSHA is (a) a listed vendor in the Federal General Services Administration's "List of Parties Excluded from Federal Procurement or Nonprocurement Programs" in accordance with Presidential Executive Orders 12549 and 12689, "Debarment and Suspension;" (b) listed in the Office of Inspector General's "List of Excluded Individuals/Entities (LEIE)" pursuant to 42 U.S.C. 1320a-7; or (c) ever been convicted of a criminal offense related to healthcare. Vendor shall notify MSHA immediately in the event that any of the aforementioned certifications becomes untrue or if Vendor is the subject of government investigation that could lead to one or more certifications being untrue. Vendor shall promptly remove any personnel from providing service on behalf of MSHA hereunder in the event such certifications become untrue with respect to such individual. This Agreement shall automatically terminate in the event that any of the certifications in this section are untrue with respect to Vendor.

3. **EEO Compliance.** Unless exempted by the rules and regulations of the Secretary of Labor, Vendor will comply, and require that its subcontractors certify compliance, with Executive Order 11246, as amended by Executive Order 11375; Section 503 of the Rehabilitation Act of 1973, as amended; the Vietnam Era Veteran Readjustment Assistance Act of 1974, as amended; and Executive Order 11625, as amended; and the rules and regulations issued thereunder. The parties do not intend that this provision confer any rights on any third party.

4. **Code of Ethics and Business Conduct.** Vendor acknowledges it has received a copy of the Code of Ethics and Business Conduct of MSHA found at: http://www.msha.com/uploads/pdf_files/MSHACodeofEthics.pdf Vendor agrees that it and Vendor personnel providing services on behalf of MSHA pursuant to this Agreement will either (i) abide by its terms and provisions; or (ii) in the event the Vendor has a substantially similar Code of Ethics and Business Conduct, abide by Vendor's Code of Ethics and Business Conduct.

5. **Product Recall.** In the event any product is to be recalled, whether voluntarily or as required by a governmental entity; Vendor shall assume all responsibility and costs for implementing such recall. Vendor shall manage the recall in accordance with applicable laws, regulations and government directives, and assume responsibility for communicating necessary details on the recall to all MSHA entities. Vendor shall pay all freight costs incurred for the return of recalled products and shall credit or reimburse MSHA for MSHA's costs in acquiring product less depreciation for actual use.

6. **Quality Requirements for Goods.** Vendor shall provide and maintain an inspection system, including tests and test reports, acceptable to MSHA in its reasonable discretion covering the inspection of goods provided under this Agreement, and Vendor shall tender to MSHA for acceptance only such goods that have been inspected in accordance with such inspection system and that have been determined by Vendor to conform to the Agreement requirements. However, all goods provided under this Agreement are subject to final inspection and acceptance within a reasonable time after actual delivery and MSHA shall have the right to reject any defective or nonconforming goods despite any prior inspection by Vendor. Payment for any goods shall not be deemed an acceptance thereof.

7. **Quality Requirements for Services.** Vendor shall provide all services required under this Agreement in a diligent manner consistent with (i) the scope of services specified in the Agreement; (ii) applicable practices and standards of diligence, care and skill currently recognized in Vendor's industry; and (iii) applicable law.

8. **Infringement Indemnity.** Vendor will defend, at its own expense, any legal action brought against MSHA to the extent that it is based on a claim that any licensed materials ("Licensed Materials") granted to MSHA by Vendor infringes a United States patent, copyright, trade secret or other intellectual property right of a third party, and Vendor will pay any costs, fees, expenses and final judgment against MSHA in any such action if attributable to any such claim or incurred by MSHA through settlement of such claim. However, such defense and payments are subject to the conditions that MSHA must: (i) notify Vendor promptly in writing of such claim, (ii) permit Vendor to have sole control of the defense, compromise or settlement of such claim, including any appeals, and (iii) fully cooperate with Vendor in the defense or settlement of such claim. Should the Licensed Material become, or in Vendor's opinion be likely to become, the subject of any such infringement claim, MSHA shall permit Vendor, at Vendor's option and expense, to (a) procure for MSHA the right to continue using the Licensed Material, (b) replace or modify the Licensed Material so that it becomes non-infringing, or (c) terminate the right to use the Licensed Material, upon which termination MSHA agrees to promptly destroy all copies of the licensed material and certify the same to Vendor, whereupon Vendor will refund MSHA's license fee on a

pro rata basis for the remainder of the license term. Vendor shall have no liability for any claim of patent, copyright or trade secret infringement that is based on (x) the use or combination of the Licensed Material with software, hardware or other materials not recommended by Vendor, provided such infringement would not have arisen but for such use or combination, (y) use of the Licensed Materials in a manner other than that for which it was designed or contemplated as evidenced by Vendor's documentation or agreement with MSHA, or (z) any unauthorized modification by MSHA or a third party on behalf of MSHA.

(9) **General Indemnity.** Vendor agrees to and does hereby defend, indemnify and hold harmless MSHA and each of its affiliates, successors, assigns, directors, officers, agents and employees ("MSHA Indemnitees") from and against any and all liabilities, demands, losses, damages, costs, expenses, fines, amounts paid in settlements or judgments, including without limitation, costs, reasonable attorneys' fees, witnesses' fees, investigation expenses, costs of management time, any and all out-of-pocket expenses, any punitive or consequential damages, and all other expenses and costs incident thereto (collectively referred to as "Damages") resulting from: (i) any claim, lawsuit, investigation, proceeding, regulatory action, or other cause of action, which may be suffered by reason of any loss, damage, death, injury, and/or other reason arising out of or in connection with products furnished or services performed by Vendor pursuant to this Agreement ("Injury"), unless the Injury was caused solely by reason of MSHA's negligence or willful misconduct; or (ii) the breach by Vendor of the warranties, representations or covenants contained in this Agreement or in materials furnished by Vendor.

10. **Insurance.** In the event Vendor is performing services on behalf of MSHA, Vendor shall, during the term of the Agreement, maintain at its own expense, (i) workers' compensation insurance coverage for Vendor's employees in each state where services are performed, pursuant to such state's requirements; and (ii) commercial general liability insurance with MSHA listed as an additional insured. Such general and professional liability insurance may be provided on either an occurrence or claims-made basis, and shall provide limits of liability in the minimum amount of one million dollars ($1,000,000) per occurrence with an annual aggregate of three million ($3,000,000).

    If any of Vendor's liability insurance coverage required above is maintained on a claims made basis, such insurance shall continue throughout the term of the Agreement; and upon the termination, expiration or non-renewal of the Agreement, or the expiration or cancellation of the insurance, Vendor shall purchase and maintain coverage for claims presented after the termination, expiration or non-renewal of the Agreement that arise from acts or events occurring during the term of the Agreement. Upon MSHA's request, Vendor shall provide MSHA with a copy of all such policies and/or certificates of insurance satisfactory to MSHA, evidencing the existence of all coverage required hereunder. Vendor shall require its insurance carriers or agents to provide MSHA, and Vendor shall also provide MSHA with not less than thirty (30) days' prior written notice in the event of a change in such policies.

11. **Independent Contractor.** No relationship of employer and employee is created by this Agreement, it being understood that Vendor and all its personnel providing services pursuant to this Agreement are and will act hereunder as independent contractors with respect to MSHA. Vendor's personnel shall not be employees of MSHA and shall not have any claim under this Agreement or otherwise against MSHA for vacation pay, sick leave, retirement benefits, social security contribution, worker's compensation, disability or unemployment insurance benefits or any other employee benefit of any kind. Vendor shall hold MSHA harmless against all liability and loss in connection with payment or nonpayment of any federal, state and local taxes or contributions imposed or required under employment insurance, Social Security and income tax laws or any other employment-related laws, including requirements for affordable health care

insurance under the Affordable Care Act, with respect to personnel furnished to MHSA by Vendor hereunder.

12. **Confidentiality.** During the term of this Agreement and surviving its expiration or termination, Vendor will regard and preserve as confidential all information related to the business of MSHA and its affiliates, clients and patients that may be obtained as the result of this Agreement. Vendor will not, without first obtaining MSHA's prior written consent, disclose to any person, firm or enterprise or use for its benefit any information relating to the pricing methods, processes, financial data, lists, apparatus, statistics, programs, research, development or related information of MSHA or their affiliates concerning their past, present or future business activities or plans, and results or terms of the sale of products or provision of services by Vendor under this Agreement. This confidentiality obligation does not apply to: (a) information that is publicly known prior to the disclosure or becomes publicly known through no wrongful act of the Vendor; (b) information that was in lawful possession of the Vendor prior to the disclosure and was not received as a result of any breach of confidentiality with respect to MSHA or its affiliates; (c) information that was independently developed by Vendor outside the scope of this Agreement, or (d) information which Vendor is required to disclose pursuant to court order or regulatory agency request. In the event of a request for disclosure falling under part (d) above, immediate notice of such request shall be provided to MSHA in order to provide an opportunity to oppose such request for disclosure. MSHA shall have the right to use Vendor pricing information on products and services for MSHA's internal analyses and may disclose such information to group purchasing organizations in which MSHA participates, counsel, consultants, advisors and potential successors in interest and purchasers.

13. **Protected Health Information.** Vendor and Vendor's personnel shall maintain the confidentiality of all patient records and data, including, without limitation, individually identifiable health information (the "Protected Health Information" or "PHI") and obtain appropriate authorization prior to any disclosure of such records and data. All title to medical records, charts, and patient files and data shall be and remain the sole property of MSHA. Notwithstanding any provision herein to the contrary, Vendor acknowledges and agrees that neither it, nor any of its personnel shall receive access to any patient information beyond that minimum amount of information necessary to accomplish the intended purpose of this Agreement. Vendor agrees that the PHI shall only be used by Vendor and its personnel for the purposes of performing pursuant to this Agreement and shall not be used for marketing, or any other purposes whatsoever, and shall only be disclosed in accordance with the terms hereof. To the extent that Vendor is a business associate, as that term is defined within the Health Insurance Portability and Accountability Act of 1996 and its privacy and security regulations promulgated pursuant thereto, Vendor shall, prior to obtaining access to PHI, execute a separate business associate agreement with MSHA that describes Vendor's obligations with regard to the possession and use of such PHI.

14. **Notices.** Notices under this Agreement shall all be in writing, effective as follows: (a) three (3) days after depositing U.S. certified or registered mail with return receipt, postage prepaid, in the mails; (b) one (1) day after sending by overnight delivery through a nationally recognized courier service; or (c) upon receipt by personal or same-day courier delivery. Unless stated otherwise provided in writing by Vendor to MSHA, notices to Vendor shall be sent to Vendor's principal address or the address specified in the Agreement. Unless stated otherwise provided in writing by MSHA to Vendor, notices to MSHA shall be sent to MSHA's address stated in the Agreement and to:

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Legal Department
400 North State of Franklin Road
Johnson City, TN 37604-6094

15. **Notices for Recalls, Alerts, and Advisories.** Notices specifically for recalls, alerts, and advisories should be sent to MSHA - The Recall, Alert and Advisory Center (TRAAC) at: TRAAC@msha.com

B. **Conflict.** To the extent that this Amendment conflicts with the Agreement or any other amendment, this Amendment shall govern.

C. **Miscellaneous.** This Amendment may be executed simultaneously in two or more counterparts (including facsimile, "pdf" and other electronic copies) each of which shall be deemed an original and all of which together shall constitute but one and the same instrument. Capitalized terms not defined herein shall have the meanings ascribed to them in the Agreement, unless otherwise specified herein. Except as set forth in this Amendment, no other changes are being made to the Agreement and the Agreement shall remain in full force and effect. The recitals are hereby incorporated into this Amendment by reference.

IN WITNESS WHEREOF, each party represents that it has caused this Amendment to be executed and delivered by an officer of such party, duly authorized, as of the date first above written.

MOUNTAIN STATES HEALTH ALLIANCE:

By: _____

Name: Timothy S. Belisle

Title: VP & General Counsel

Date: 2/2/15

VENDOR:

By: _____

Name: Sam Courey

Title: CFO

Date: 2/3/15

APPROVED BY MSHA CORPORATE CONTRACTS
MSHA LEGAL DEPARTMENT APPROVAL NOT REQUIRED

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Attachment 6.Section C, Need. Item 5

(Historical Utilization in PSA)

County	Facility and Type	Number of MRI Scanners and Type	Distance from Applicant (miles)	Total Procedures			Percent Changed 2011-2013	Patient Referrals by Med Care Physicians in 2014[1]
				2011	2012	2013		
Washington	Franklin Woods Community Hospital (HOSP)	1 Fixed	8.74	3546	3499	3529	-.48%	207
Washington	Johnson City Medical Center (HOSP)	2 Fixed	8.12	7247 (avg. 3623.5 per scanner)	7237 (avg. 3619 per scanner)	6617 (avg. 3308.5 per scanner)	-8.69%	159
Washington	Mountain States Imaging at Med Tech Parkway (ODC)	1 Fixed	8.69	2738	2697	2448	-10.59%	20
Washington	Watauga Orthopaedics, PLC (PO)	1 Fixed	7.16	2748	2415	2337	-14.96%	0
Washington	Appalachian Orthopaedic Associates - Johnson City (PO)	1 Fixed	8.35	546	357	188	-65.57%	0
~~Sullivan~~	~~Appalachian Orthopaedic Associates - Kingsport (PO)~~[2]	~~1 Fixed~~	—	~~1460~~	—	—	—	---
Sullivan	Appalachian Orthopaedic Associates, PC (PO)	1 Fixed	16.67	288	268	214	-6.63%	0
Sullivan	Bristol Regional Medical Center (HOSP)	2 Fixed	16.67	6447 (avg. 3223.5 per scanner)	6578 (avg. 3290 per scanner)	6323 (avg. 3161.5 per scanner)	-1.92%	0
Sullivan	Holston Valley Imaging Center, LLC (ODC)	3 Fixed	22.49	8362 (avg. 2787.3 per scanner)	8792 (avg. 2931 per scanner)	8787 (avg. 4393.5 per scanner)	5.08%	0
Sullivan	Holston Valley Medical Center (HOSP)	1 Fixed	22.45	3774	3514	3326	-11.87%	0
Sullivan	Indian Path Medical Center	1 Fixed	20.63	2651	3000	2807	5.88%	0

[1] These figures are only estimates because Medical Care does not track information pertaining to which facility its patients receive MRI scans. MRI appointments are made via Mountain States Health Alliance's centralized scheduler and that entity (not Medical Care) selects the facility where a scan will be performed.

[2] This unit was sold in 2012

Sullivan	Meadowview Outpatient Diagnostic Center	1 Fixed	21.45	4457	4484	4350	-2.40%	10
~~Sullivan~~	~~Wellmont Sapling Grove Imaging, LLC (Stand up MRI) (HImaging)~~[3]	~~1 Fixed~~	—	~~349~~	~~150~~	—	—	—
Sullivan	Sapling Grove Outpatient Diagnostic Center (ODC)	1 Fixed	16.64	2587	2309	2245	-13.22%	0
Sullivan	Volunteer Parkway Imaging Center (HODC)	1 Fixed	15.46	1327	1348	1239	-6.63%	0
Unicoi	Unicoi County Memorial Hospital, Inc. (HOSP)	1 Fixed	17.30	1630	1164	935	-42.64%	0
Johnson	Johnson County Community Hospital (HOSP)	1 Mobile (2 days/month)	26.10	274	308 (4 days)	267 (4 days)	-2.55%	0
Carter	Sycamore Shoals Hospital (HOSP)	1 Fixed	.22	1958	2014	1719	-12.21%	296

[3] This unit was sold in 2012.

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Attachment Section C, Economic Feasibility Item 1.

SUPPLEMENTAL- 1

PROJECT COSTS CHART

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A.	Construction and equipment acquired by purchase:	
1.	Architectural and Engineering Fees	0
2.	Legal, Administrative (Excluding CON Filing Fee), Consultant Fees	5,000
3.	Acquisition of Site	0
4.	Preparation of Site	0
5.	Construction Costs	0
6.	Contingency Fund	0
7.	Fixed Equipment (Not included in Construction Contract)	0
8.	Moveable Equipment (List all equipment over $50,000)	0
9.	Other (Specify) _____	0
B.	Acquisition by gift, donation, or lease:	
1.	Facility (inclusive of building and land)	
2.	Building only	
3.	Land only	
4.	Equipment (Specify) MRI	$549,051.90
5.	Other (Specify) facility lockers	$2,499.60
C.	Financing Costs and Fees:	
1.	Interim Financing	0
2.	Underwriting Costs	0
3.	Reserve for One Year's Debt Service	0
4.	Other (Specify) _____	0
D.	Estimated Project Cost (A+B+C)	$556,551.50
E.	CON Filing Fee ($1,252.23)	$3,000.00
F.	Total Estimated Project Cost (D+E)	
	TOTAL	$559,551.50

SUPPLEMENTAL- 1

TOSHIBA
Leading Innovation >>>

May 28, 2015
12.25pm

TOSHIBA AMERICA MEDICAL SYSTEMS, INC.

QUOTATION/ORDER
ORDER SUMMARY

SID NO: 30012104
DATE: 9/25/2014 QUOTE NO: 57064-6

PRESENTED TO: (COMPLETE LEGAL NAME)

SYCAMORE SHOALS HOSPITAL
1501 W ELK AVE
ELIZABETHTON, TN. 37643

DELIVER TO:

SYCAMORE SHOALS HOSPITAL
1501 W ELK AVE
ELIZABETHTON, TN. 37643

EQUIPMENT SUMMARY:

TITAN.000	**TITAN HIGH FIELD MRI SYSTEM**	$687,996.00
	PRE-INSTALLATION KIT FOR TITAN	
	MRI SYSTEM MAGNET	
	TITAN SYSTEM ELECTRONICS WITHOUT MAGNET	
	ASGC FOR TITAN WITHOUT HIGH ORDER SHIM	
	WATER DISTRIBUTION PANEL	
	MEDIA FOR DVD-RAM DRIVE (9.4 GB) (Qty 5)	
	GATING WAVEFORM LCD DISPLAY	
TITAN8-16CH.100	TITAN 8-CHANNEL TO TITAN 16-CHANNEL RF ELECTRONICS (FACTORY OPTION)	$119,418.00
	16-CHANNEL RF ELECTRONICS	

This quotation shall remain valid until September 30, 2014.
All prices are F.O.B. destination.
Payment terms are: Cash - 0% down payment, 80% upon shipment, 20% net 30 days after shipment or upon availability for first use by purchaser, whichever comes first.

Additional terms and conditions appear at the end of this quotation. McKesson Agreement Required _____Yes _____No
Vital Software License Agreement Required _____Yes _____No
Please return signed quotation to: Toshiba America Medical Systems, 2441 Michelle Drive, Tustin, CA 92780 or fax to either number.
Fax: 714/669-4578 or 714/669-1762 Attention: Quote/Order Department.

ACCEPTED AGREED AND ORDERED:

CUSTOMER REQUESTED DELIVERY DATE: _____ _____ _____
TOSHIBA REP/CONTACT DATE

_____ _____ _____ _____
PURCHASER'S SIGNATURE/TITLE DATE ZONE SALES MANAGER DATE

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May 28, 2015
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TOSHIBA AMERICA MEDICAL SYSTEMS, INC.

QUOTATION/ORDER ORDER SUMMARY

DATE: 9/25/2014

SID NO: 30012104
QUOTE NO: 57064-6

PRESENTED TO: (COMPLETE LEGAL NAME)

SYCAMORE SHOALS HOSPITAL
1501 W ELK AVE
ELIZABETHTON, TN. 37643

EQUIPMENT SUMMARY: (continued)

	MBODY PACKAGE FOR TITAN	
	SOFTWARE, MBODY PACKAGE	
MJAB-167A/P1	TITAN BODY COIL	$35,418.00
	MVASCULAR KIT FOR TITAN	
	MVASCULAR PACKAGE	
	FREEZE FRAME PACKAGE FOR VANTAGE	
	NON-CONTRAST MRA AND SUPERFASE PACKAGE	
	MNEURO PACKAGE FOR TITAN	
	MNEURO PACKAGE	
	BODY VISION AND DTI PACKAGE FOR VANTAGE	
	DIFFUSION TENSOR TRACTOGRAPHY APPLICATION	
GATING-W/T.100	GATING PACKAGE -- WIRELESS	$10,611.00
	WIRELESS CARDIAC GATING UNIT	
	WIRELESS PERIPHERAL / RESPIRATORY GATING PACKAGE	
	DICOM STORAGE COMMITMENT KIT	

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	DICOM Q/R SCP UNIT	
	VIDEO FADER	
	CONSOLE DESK 65" X 36" X 30"	
	SILENT SCAN STEREO AND INTERCOM SYSTEM	
	LCD MONITOR FOR ECG	
	ELECTRODE PADS (BOX OF 25) (Qty 2)	
	PATIENT PADS FOR SPINE AND EXTREMITY	
	OVERHEAD CABLE INSTALLATION	
	GANTRY LIGHTING OPTION	
VRDU-TITAN-U4-H	TEAL VRDU FOR TITAN U4, 480V	$30,900.00
PACT78S3-T4-ZTM.001	DRAKE HEAT EXCHANGER DUAL LOOP 460 FOR TITAN OR ATLAS Z	$30,847.00
MZPT-1510/S3	TITAN HIGH CAPACITY TABLE - FACTORY OPTION	$35,418.00
MJAJ-197A/J1	4-CHANNEL FLEX SPEEDER COIL	$13,706.00
MJAJ-227A/S1	16-CHANNEL FLEX SPEEDER LARGE COIL	$22,077.00
MJCA-207A/S1	FLEX COIL POSITIONING PAD SET	$5,431.00
MBREAST-T.100	MBREAST PACKAGE	$3,542.00

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	SOFTWARE, MBREAST	
4000235-11-12	RADIANCE PLUS BREAST IMAGING PACKAGE FOR TITAN	$68,123.00
MR-TRAINING-99	MR BREAST IMAGING COURSE - IRVINE	$3,000.00
MJAH-167A.100	OCTAVE HEAD SPEEDER COIL KIT	$46,633.00
	OCTAVE HEAD SPEEDER COIL	
	TILTABLE OCTAVE HEAD COIL BASE	
MJAJ-177A/S1	SHOULDER SPEEDER COIL	$33,485.00
MJAS-147A/E1	ATLAS SPINE COIL	$41,320.00
MBPS-1503/S1	RAPID TRANSPORT SYSTEM - RIGHT	$33,830.00
WSAE-HW-0002.100	AEGIS CAD WORKSTATION SINGLE USER	$35,908.00
	AEGIS CAD WORKSTATION SINGLE USER	
	AEGIS BASE (MM) PLATFORM	
	AEGIS BASE LICENSE	
	AEGIS BREAST LICENSE	
	AEGIS BREAST PLUG-IN	
	DELL 27" COLOR DISPLAY	

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AEGIS LAPTOP COMPUTER (BIOPSY ONLY)

AEGIS BREAST BIOPSY LICENSE

NET PRICE $1,257,663.00
Applicable Sales Tax Additional

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Special Information & Terms

- Special Group Buy Pricing. This price is offered contingent on the receipt of a purchase order and executed quotation by 12:00PM, Pacific Standard Time, September 30, 2014.

- This quotation/order will be subjected to the Agreement for Magnetic Resonance Imaging equipment products between Premier Purchasing Partners, L.P. and Toshiba America Medical Systems, Inc., effective July 15, 2014. Reference contract no. GB-IM-200C.

- This quotation includes twenty-four (24) month system warranty (excludes consumables, vended items, etc.). Customer will be required to execute a non-cancelable five-year Toshiba Full Service Maintenance Agreement at the time of equipment order. Toshiba America Medical Systems, Inc. provides service labor coverage during the twenty-four (24) month warranty period at no charge to the customer between the hours of 8 a.m. - 5 p.m., Monday through Friday, excluding federal holidays.

Quotation includes services described in attached quotation from Physica Imaging, LLC in an amount not-to-exceed $6,000.

Customer hereby acknowledges and agrees that solely as a convenience to Customer, Toshiba is entering into an agreement with a Vendor in order for to sell, deliver, install, and service its products, and perform other work to and for the benefit of Customer. However, Customer hereby agrees that Toshiba will not be liable for any defects in design, material and workmanship in the products or services sold and/or performed by Vendor or otherwise be responsible for such products or services. Customer will have no rights or remedies against Toshiba for such products or services. Customer's sole remedy will be against Vendor.

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TITAN.000 TITAN HIGH FIELD MRI SYSTEM

Fast, powerful and easy to use, Vantage Titan provides patients with the most comfortable, non-claustrophobic MR imaging environment available in the market. Titan combines diagnostic versatility with streamlined workflow, from routine examinations to whole-body scans and MRA from head-to-toe, including Toshiba's proprietary non-contrast techniques.

Highlights include:

- Open-bore technology with a 71 cm patient aperture, designed to reduce claustrophobia and increase patient comfort
- The speed and image quality of Integrated Coil Solutions
- The unsurpassed technology of the world's highest homogeneity ultra-short-bore magnet

The system's large clinical field-of-view (FOV) – 55x55x50 cm – produces high-quality images without compromising homogeneity or overall imaging performance. Only Toshiba offers a 55-cm field of view with a 1.49-meter magnet.

Titan simplifies patient repositioning while still allowing excellent image quality, featuring Integrated Coil Technology that uses up to 128 elements simultaneously, a moveable spine coil, wide-area coverage and extended table travel that enables feet-first imaging.

Toshiba's proprietary non-contrast MRA techniques, now in their fourth generation, minimize risk to patients while delivering superb images. The new M-Power state-of-the-art user interface is designed to maximize ease-of-use and efficiency.

Vantage Titan offers a scalable solution to meet any customer's clinical needs with the highest level of patient comfort and diagnostic capability all in one package.

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KEY COMPONENTS

- Magnet with actively shielded gradient coil (34 mT/m, SR 148)
- Open bore featuring a 71 cm patient aperture
- 8-channel array electronics standard
  - Optional 16 RF Channel Kit - MKPA-1506/S1
  - Optional 32 RF Channel Kit - MKPA-1505/S1
- SPEEDER package, including high-speed reconstruction engine capable of 12,600 images/sec
- 9.4 GB DVD ROM drive
- Oxygen monitor and emergency run-down unit
- QD Titan whole body coil
- Patient monitoring camera and LCD display for the technologist
- Cardiac, peripheral and respiratory gating
- Pianissimo Plus imaging package
- UPS for Host Computer to prevent damage during power problems
- Accessories (positioning pads, arm rest, DVD media (set of five), and electrodes/ECG leads)

PERFORMANCE FEATURES

The system's integrated coils and enhanced speed combine with a digital-RF Xeon platform and high-performance gradients to enable a wide range of imaging techniques while providing unsurpassed flexibility and patient comfort.

Patient Comfort

Titan reaches a new level in patient comfort with its open-bore technology featuring a 71 cm patient aperture.

Titan's clinical efficiency also enhances the patient experience, with features that enable feet-first imaging and coil combinations that virtually eliminate the need for repositioning.

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Pianissimo™ Noise Reduction System
Pianissimo noise-reduction technology, standard on all Titan systems, uses a unique vacuum-sealed chamber to dramatically reduce acoustic sound levels making patients more cooperative and comfortable. There is no compromise in image quality or speed of acquisition.

Pianissimo is always on – there is no user interaction required or special sequences that need to be selected.

Pianissimo Plus Imaging Package
Imaging sequences designed to further reduce the already-quiet Pianissimo noise-reduction technology.

Lighting and Ventilation
- New track lighting inside the bore of the magnet provides a much brighter environment for the patient.
- Air vents have been positioned high on the rear of the magnet bore to provide increased airflow to the patient.

Integrated Coils
- 10 integrated coil ports to position multiple coils simultaneously
  - Nine on the patient couch
  - One on the magnet gantry
- Can accept up to 128 elements simultaneously
- Reduces the need to change coils between studies
- Integrated, moveable spine coil
- Integrated posterior head and neck array
- Light-weight for improved flexibility and patient comfort

Extensive Coverage
- Extended table travel option allows (205 cm) of table movement for greater flexibility
- Moveable spine coil to accommodate feet-first imaging
- Extended clinical field-of-view: 55x55x50 cm

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Patient Call and Intercom System

- A hand switch enables the patient to signal an emergency during scanning.
- The integrated intercom system allows for the patient and operator to speak to each other.

SPEEDER Package

This parallel-imaging technology offers:

- Higher temporal resolutions for dynamic imaging
- Higher spatial resolutions for acquiring images in a shorter time

JET Motion Correction Software

JET imaging detects the amount of motion and corrects for the effect by acquiring k-space data in a radial trajectory. Data in the center of k-space is acquired multiple times during the scan to suppress motion artifact. Two kinds of motion, rotational and translational, are evaluated and corrected.

- Reduces motion artifact caused by physical movement as with acute stroke, uncooperative or pediatric patients
- Reduces motion artifact caused by physiologic motion, such as CSF flow and breathing
- Reduces respiratory artifacts for the shoulder and abdominal regions

mVox

- Allows isotropic, FSE, 3-D volume acquisitions, which can then be reformatted into multiple imaging planes to increase efficiency and reduce patient imaging time.
- Can be used with T2 and T2 FLAIR contrasts.

Reconstruction Engine

A high-speed computer that reduces reconstruction times in all imaging modes. Conventional images with a 256x256 matrix are reconstructed at a rate of 12,600 images/sec.

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Conventional Pulse Sequences

SE (Spin Echo)
- Proton density
- T1 and T2 weighted contrast

FE (Field Echo)
- Varied flip angle to optimize contrast and SNR
- Provides T1 and T2* weighted images

IR (Inversion Recovery)
Generates desired contrast for STIR, FLAIR and T1 heavily weighted images.

Fast Scan Sequences

FastSE (Fast Spin Echo)
- Compatible with 2-DFT and 3-DFT
- Short and variable echo-train spacing available

FastIR (Fast Inversion Recovery)
- Enhances T1 contrast to a 2-DFT FastSE technique

FastFLAIR (Fluid Attenuated IR)
- Increases contrast between fluids and tissues such as CSF
- Shorter scan times than conventional IR

FastSTIR
- Suppresses fat signal with short TI
- Shorter scan times than conventional STIR

FastFE
- Provides T1 contrast with short scan times
- A useful breath-hold technique
- 2-DFT and 3-DFT applicable

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Advanced Fast Scan Techniques

FASE (Fast Advanced Spin Echo):
An RF-refocused imaging technique that broadens clinical applications such as MRCP (MR cholangio-pancreatography), urography and myelography.

- Combined with half-Fourier imaging, reduces scan times dramatically
- Can be used with both 2-DFT and 3-DFT
- Provides high-contrast, T2-weighted images
- Large number of echoes
- Provides echo factors up to 512 or, with optional software, 1024

EPI (Echo Planar Imaging):
Hybrid EPI that uses a combination of spin and gradient echoes in one acquisition to reduce SAR.

- Multiple echo-train lengths available
- SE-based techniques provide T2-weighted contrast while reducing SAR
- Multi-Shot EPI also included

True SSFP (Steady State Free Precision):

- Rapidly obtains T1 or T2 weighted contrast images
- Well suited for tissues with longer T2 values
- 2-D and 3-D sequences included

T2 Plus FastSE/FASE:
Provides reduced scan times, higher resolution capabilities and increased SNR by refocusing residual transverse magnetization back to longitudinal per TR with no compromise in T2 contrast.

SSFP (Steady State Free Precision):

- Provides images with T1 or T2 weighted contrast
- Well-suited for CSF or synovial fluid imaging
- Can be applied in a 2-D or 3-D mode

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Advanced Pulse Sequences

- Digital RF capabilities provide precise phase control
- Suitable for T1-weighted sequences with short TR and TE

MR Fluoroscopy:
Continuously acquires and reconstructs data and displays the reconstructed image immediately.

Real-Time Locator:
Advanced application of MR Fluoroscopy, which acquires three planes to facilitate patient positioning.

Vascular Imaging Techniques

Fine vascular structures are visualized with various innovative techniques.

- 2-D Time-of-Flight (TOF)
- 3-D TOF
- Multi-slab 3-D TOF
- Multi coverage – separates large 3-D TOF slabs to minimize saturation of blood in fine distal vessels
- 3-D FE and 3-D FastFE – for contrast-enhanced MRA applications
- SORS-STC (Slice Selective Off-Resonance Sync Pulse Saturation Transfer Contrast) – applies Magnetization Transfer Contrast (MTC) pulse to individual slices, resulting in a more robust magnetization transfer technique
- ISCE (Inclined Slab for Contrast Enhancement) – increases vessel detail by using variable flip-angle RF pulses with 3-D TOF to enhance the contrast from blood flow throughout the volume
- 2-D phase shift (PS)
- Cine 2-D PS – used with cardiac gating unit for cine imaging
- Flow quantification – measures blood flow velocity using cine 2-D PS and cardiac gating
- 3-D PS
- BEST (Blood Vessel Enhancement by Selective Suppression Technique) – a post-processing algorithm to selectively enhance small-vessel detail and suppress background tissue

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Fat Free Imaging

Coupled with Vantage's superior homogeneity, various sequences provide uniform and consistent fat suppression over the imaging area. Sequences include:

- STIR
- Fast STIR
- WFOP (Water/Fat Opposed Phase) – a Spin Echo technique that acquires signals from water and fat as they go in and out of phase
- MSOFT (Multislice, Off-Resonance, Fat-Suppression Technique) – a Toshiba exclusive for fat suppression using a slice-selective, offset RF pulse for each slice
- PASTA (Polarity Altered Spectral and Spatial Selective Acquisition) – a water-excitation technique for FSE and SE fat-signal suppression
- DIET (Dual Interval Echo Train) – reduces bright, fat signal in Fast Spin Echo sequences by varying inter-echo spacing

Cardiac Gating Package

Acquires ECG data to identify the cardiac cycle during scan acquisition. Multislice/single-phase and single-slice/multi-phase modes can be used. The unit consists of:

- Gating manager
- LCD monitor
- Patient lead wire
- ECG electrodes
- Set of connection cables
- Set of accessories
- Operator's manual

Respiratory Gating Package

Compensates for motion artifacts caused by patient breathing and chest movement. Monitors respiratory motion and transmits the signal through the cardiac gating electronics. The package consists of:

- Respiratory sense box
- Air bag and belt

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- Set of accessories
- Operator's manual

Peripheral Pulse Gating Package

Used to synchronize slice data with the patient's cardiac cycle when imaging. Monitors pulse from the patient's finger and sends the signal to the scanner through the cardiac gating unit electronics. The package consists of:

- Pulse-wave, pick-up sensor with 1.5 m optical fiber
- Set of accessories
- Operator's manual

M-Power Productivity Features

Titan 1.5T employs the new M-Power interface designed for intuitive scanning, enabling even those with less experience to operate the system without difficulty.

Created with universal design concept to be user-friendly, reduce operator stress and facilitate efficient workflow.

New image-processing engine provides:

- 3-D image processing and color-fusion processing
- Flexible support for clinical application software

The software is designed to facilitate easy integration in the widest variety of network environments for patient registration, scan planning, image review, and filming and archiving for maximum efficiency and productivity.

- High-resolution, 24", LCD color monitor with display matrix of 1,280x1,024 with 256 B/W gradation levels
- Calendar for advanced patient scheduling and registration
- DICOM-compliant to facilitate easy integration with other network environments

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- Pre-programmed protocols – accessed by a mouse-click over an anatomical icon, this integrated smart software eliminates guesswork and provides clinical flexibility and productivity
- Graphic scan planning – easy-to-understand graphics and prompts to quickly plan subsequent exams and input last-minute sequence-parameter selections on all three orthogonal planes
- Image selector – displays visual table of contents for quick and simple image display of complete studies
- Batch MIP and CINE display while continuing other functions
- Extensive post-processing algorithms for image enhancement
- Two-way patient intercom system
- Patient monitoring camera and LCD display for the technologist

General Hardware Description

1.5T Self-Shielded, Open, Ultra-Short-Bore Magnet

A combination of passive and auto-active shimming provides optimum homogeneity and uniformity for maximizing imaging results.

- Homogeneity specified at 2 ppm (guaranteed value) or less over 50 cm DSV (50x50x50 cm) using a 24-plane plot VRMS method.
- 71 cm patient opening and 1.49-meter magnet ensure maximum patient comfort and accessibility.
- Productivity features such as scan start, localizers and couch control are incorporated on both sides of the bore.

Patient Couch

Atlas features a coil solution integrated into the couch for maximum patient comfort and increased technologist productivity. Couch also includes manual, automatic and emergency controls to facilitate patient handling for routine and extraordinary conditions.

- Nine coil ports are integrated into the patient couch; one additional port located on the magnet gantry
- Hydraulically controlled bed lowers to 16.5" (42 cm) from the floor
- Includes multiple couch mats and positioning pads for greater comfort

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- Includes bilateral arm rests to facilitate injections
- Maximum patient weight of 440 lbs (550 lbs optional)

Titan Gradient Subsystem

Precision and reliability are integrated into Toshiba's gradient subsystem.

- Powered with a 148 T/m/sec slew rate and 34 mT/m gradient strength.
- 229 ms rise time enables generation of complex gradient pulses.
- Maximized clinical performance with Toshiba's actively shielded gradient coil – virtually eliminates eddy currents from the magnet while maintaining gradient linearity.

Digital RF System

Titan comes standard with a digital RF system with 8 RF channels supporting array acquisition. The digital transmitter provides the precise RF phase control needed to employ advanced pulse sequences. The high-frequency data sampling capability supports fast scan techniques.

M-Power Computer System

Provides outstanding multi-tasking performance. Image reconstruction and advanced image processing are performed simultaneously with scanning to increase exam productivity. The system includes network connectivity for expandability.

Host Computer Includes:

- Intel® Xeon™ 6-core 12 CPU system
- Clock speed: 2.4 GHz or more
- 2 hard disk drives
- 12 GB or more of main memory
- 300 GB hard drive for system use (unformatted storage)
- 600 GB hard drive for image data (unformatted storage)
- Stores approximately 1,120,000 images (256x256 images)
- 32-bit CPU
- 256 MB memory capacity

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Reconstruction System

- 6-core dual-processors system
- Reconstruction speeds up to 12,600 images/second (256x256,FFT)
- Simultaneous image reconstruction during scanning
- Reconstruction matrix up to 1,024x1,024
- Main memory capacity: 12 GB or more
- 3.5TB hard disk drive (unformatted storage)

DVD Drive Unit

- 9.4 GB storage capacity (unformatted storage)
- Up to 44,000 saved-image capacity (256x256 images)

Connection With External Devices

- Ethernet interface (1000BASE-T)
- DICOM 3.0

Auto Voice Package
Provides pre-recorded patient instructions to use during scan acquisition. Messages can be edited and re-recorded by the operator.

Networking DICOM Licenses

DICOM Basic License
Provides the basis for DICOM on the MRI system.

DICOM MWM Modality Worklist Management
Allows the scanner to manually or automatically pull work orders scheduled on RIS from Broker.
Note: RIS Broker is not included.

DICOM Print Service Class User (SCU)
This provides a connection to a DICOM-compliant Service Class Provider (SCP) laser camera or film imager.

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DICOM Storage Service Class User (SCU)
This allows the MRI scanner to push images out to multiple destinations on a network which is connected to the scanner.

Image Maker Express Marketing Support
Image Maker Express is an online marketing resource that helps Toshiba customers build demand for imaging service by growing their referring physician and patient relationships. Image Maker Express includes:

- Easy-to-use marketing resources and tools developed exclusively for Toshiba customers to bring together effective marketing strategies and tactics.
- A wealth of collaterals and content to create high-quality brochures, print ads and more to help market the Toshiba customer's new imaging capabilities.

Image Maker Express Materials available include:
- Product images and logos
- Clinical images and videos
- PowerPoint presentations and promotional videos
- Brochure samples
- Customizable press releases and media tips
- Marketing strategy tutorials

**Offerings may vary per product*

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APPLICATIONS SUPPORT

Each system includes three phases of operator training.

Phase I: Two vouchers for a one-week intensive course at the Toshiba Education Center in Irvine, California.

- One technologist must attend prior to system installation
- Travel expenses included
- The second voucher is valid for six months following installation
- Additional vouchers available for $3,500

Phase II: Two weeks of on-site training at the customer's facility.

- For one to four technologists
- Covers operation of the complete system including set up of customized scan protocols

Phase III: On-site training to follow up on questions, review key areas and address requests for advanced imaging procedures.

- 32 hours of training
- Four to six weeks after the initial training
- For one to four technologists

Performance Pro

Performance Pro is a custom program created to offer a unique approach to education, focusing on achieving technical proficiency and optimal productivity. The program includes the following:

- A planning meeting at your facility with Toshiba's MRI Applications Manager. The purpose of the meeting is to discuss objectives and timing, and to explain Toshiba's custom approach. During the meeting the manager also will ensure that the following takes place:

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- Review Toshiba's New Customer Education Guide (what to expect and how to plan and prepare).
- Introduce the Toshiba Three Phase Education Program and the role of the Toshiba Education Center.
- Co-develop a custom training program based on the facility's specific needs and ensure it is well documented for execution.

- A trained Applications Specialist will be assigned ownership of the education experience for the facility. They will perform the following duties:
  - Participate in planning meetings with the project team to address any training issues in a proactive fashion.
  - Communicate with the facility prior to the turnover date to ensure everything is on track and all questions or concerns are addressed.
  - Ensure all materials (training manuals and learning aids) are on site at the time of the go-live date.

- A Quality Installation Checklist developed by Toshiba's service team and physicists will be used to ensure all system requirements have been met and the scanner is working properly and yielding good image quality.

- A Clinical Evaluation will be conducted by a National Clinical Support specialist prior to the turnover to ensure the system is ready for go-live date. The specialist will communicate approval to the Applications Manager, the assigned Applications Specialist, the Account Executive and the Service Team.

- Consistent on-site service support during the turnover.

- The Toshiba Education Center will properly train and prepare the core trainers to perform their role with the most advanced education approach in the industry.

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- Toshiba will send two Application Specialists to the turnover. One will work with technologists for two consecutive weeks (the assigned Applications Specialist) and the other will work with physicians for one week to achieve desired image quality.

- At the start of the turnover, Toshiba will begin with a presentation for the staff and referring physicians to highlight system capabilities and generate excitement.

- Performance Pro is a blended learning approach and includes prerequisites and additional accredited CE courses for the clinical staff.

A special visit will be conducted by National Clinical Support Specialist four to six weeks after turnover to check protocols and image quality. The specialist will be available to meet with physicians and technologists to answer all questions.

Additional On-Site Training
Additional On-site training available for purchase.

InTouch Center®
This centralized service facility provides applications and service support for Titan 1.5T customers 24 hours a day, seven days a week.

InnerVision™ Plus
Remote system diagnostics are available around-the-clock to help identify problems and provide potential solutions before care is interrupted or an engineer can arrive.

InTouch Agreements
Based on customer needs, InTouch customer agreements can range from an a-la-carte approach to full-security agreements that provide complete system protection.

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Technical Assistance
Customer support specialists are available 24/7 to help resolve technical issues in real time. Application support specialists are also available to assist staff with protocol and image-quality issues.

Service Support
Local Customer Teams
A single call mobilizes a local team of Toshiba customer engineers. With an average of 10 years of Toshiba experience and 105 hours of specialized training, they can resolve almost any performance issue.

Parts Support
A complete inventory of Titan 1.5T product parts is ready for shipment when and where they are needed, any time of day or night.

Installation
Toshiba's installation coordinator and Atlas site planning guide are made available to facilitate site planning. All installation and standard rigging costs are included.

Note: RF Shielding and RF Room are not included or provided by Toshiba

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COMPONENT SUMMARY:

PRE-INSTALLATION KIT FOR TITAN

MRI SYSTEM MAGNET

TITAN SYSTEM ELECTRONICS WITHOUT MAGNET

ASGC FOR TITAN WITHOUT HIGH ORDER SHIM

WATER DISTRIBUTION PANEL

This custom-designed manifold standardizes on-site plumbing for all Toshiba MRI systems. It distributes chilled water to all MRI processes, contains all required valves, flow meters, temperature gauges, and pressure gauges.

MEDIA FOR DVD-RAM DRIVE (9.4 GB) (Qty 5)

- 9.4 GB
- Two-sided

GATING WAVEFORM LCD DISPLAY

Displays physiological signals (ECG, respiration, peripheral). Mounted on the magnet front so a single operator can verify proper ECG lead placement from the magnet room.

TITAN8-16CH.100

TITAN 8-CHANNEL TO TITAN 16-CHANNEL RF ELECTRONICS (FACTORY OPTION)

16-CHANNEL RF ELECTRONICS

The 16-channel RF electronics kit includes the hardware and components to take the 8-channel to a 16-channel RF system.

MBODY PACKAGE FOR TITAN

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SOFTWARE, MBODY PACKAGE

MJAB-167A/P1 TITAN BODY COIL

Titan 16 channel RF configuration
16-element array design is suitable for chest, cardiac, abdominal and pelvic studies with an extended field of view (EFOV) with 50 cm of coverage as well as optimal signal-to-noise ratio.

- Works with the Atlas Spine Coil to create a 32-element array.
- Combine with Atlas Head/Neck and Atlas Spine Coil or with two other body coils for full-body coverage.

Titan 8 channel RF configuration
The body coil creates an 8 element array when combined with the integrated spine coil.

Note: Standard Atlas Body Coils cannot be used on the Titan system.

MVASCULAR KIT FOR TITAN

MVASCULAR PACKAGE

The M-Power mVascular Software Package contains pulse sequences and imaging functions to perform Contrast MRA, Dynamic Contrast MRA (Freeze Frame) and Contrast Free MRA exams.

MRA Software includes:

Visual Prep
Enables the technologist to begin scanning at the optimal time by observing the contrast medium as it flows to the target region. By using subtraction techniques, images can be displayed even more clearly and without signal inversion.

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- Other features of VisualPrep include:
- WB coil scanning:
  - View the contrast flow using the WB coil while conducting the main scan with the optimal receive coil.
  - This includes all coils supporting the SPEEDER technique.
- Dynamic scan:
  - Execute VisualPrep at the start of the second segment and subtract images automatically in post-processing.
  - Acquire arterial phase images in the first segment and venous-phase images in the second.
- Moving Bed:
  - Specify in each stage of MovingBed.
  - Acquire images without contrast, then start contrast images at optimal time.
- Gated Scan: Image the heart in synchronization with cardiac contraction.

Moving Bed
Allows MRA to be performed over a wide range, such as from the chest or abdomen to the lower limbs, by moving the couch-top between scans.

- Set optimal couch-top slide distances according to the flow speed of the contrast.
- Use with VisualPrep to start scanning at the optimal time.
- Enable effective fat suppression by performing shimming acquisition semi-automatically in advance at each couch-top position.

STAMD
Depicts the spatial relationship between blood vessels more clearly by changing the slice range for MIP processing in a step-by-step manner.

Dynamic Complex Data Subtraction
To prevent signal inversion in the blood vessels, perform subtraction between the dynamic images and the reference image that is acquired before contrast medium injection. Subtraction is available automatically after data acquisition is completed.

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Fat Suppression in FFE 3-D Swirl Encode Imaging
The increase in the scan time is minimized by applying the fat-saturation pulse most effectively.

FREEZE FRAME PACKAGE FOR VANTAGE

Differential Rate K-space Sampling (DRKS) provides an increase in temporal resolution without sacrificing scan resolution.

- Eliminates the need for bolus timing as multiple, high-resolution dynamic images are produced per scan.
- Uses a sophisticated method of sampling k-space by segmenting it into several parts, allowing centric segment data to be acquired more frequently.

NON-CONTRAST MRA AND SUPERFASE PACKAGE

Provides pulse sequences effective for non-contrast vascular imaging, cardiac imaging and functions that expand the range of clinical applications.

Fresh Blood Imaging (FBI)

- Produces angiograms and venograms without the use of contrast.
- Combines ECG gating with (FASE) Fast Advanced Spin Echo pulse sequences.
- Acquires arterial and venous flow in one acquisition, which can be viewed together or separately using an automated subtraction technique.
- Integrated Atlas SPEEDER coil technology allows multiple consecutive stations to be imaged. These stations can be automatically stitched together, creating one large field-of-view image that depicts vasculature from above the femoral bifurcation to the feet.

Contrast-Free Improved Angiography (CIA) – Flow Spoiled FBI

- An extension of Fresh Blood Imaging using additional flow spoiler gradients to produce a stronger separation between arterial and venous flow signals.

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- Uses a flow preparation scan to optimize the effectiveness of the Flow Spoiler pulses. This ensures that the optimal Flow Spoiler value is selected.
- The improved visualization of slower vascular flow is especially useful for diabetic patients with compromised circulation.

Time-SLIP (Spatial Labeling Inversion Pulse)

- Based on Arterial Spin Labeling, uses a non-selective spatial inversion pulse, spatial tag pulses and natural blood as its own tracer.
- Applicable in multiple regions of the body for both hemodynamic velocity and vascular visualization.
- Especially useful for imaging complex vessels flowing in multiple directions, such as renal arteries, portal venous system and pulmonary arteries.
- Can be used as a non-contrast MRA option for the carotid arteries.

TSA

Non-contrast, time-resolved, head-and-neck blood flow using the Time-SLIP technique with variable BB-TI times.

Time-SLIP BB TI

Non-contrast vascular imaging of the abdomen and lung fields with Time-SLIP Optimization.

- Determines optimal BBTI in FASE imaging by varying the TI at regular intervals.
- Programmable parameters are the:
  - Initial TI value (unit: lms)
  - Interval (1 to 500 ms)
  - Number of repetitions (max 1000)

SPEED (Swap Phase Encode Extended Data Acquisition)

For non-contrast vascular imaging.

- Acquires two images with phase encode directions shifted by 90 degrees for the same slice in a single scan. Then combines the images using a composite MIP post-processing technique.

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- The matrix and FOV scanning parameters are automatically set to square.
- Respiratory gating can be combined with cardiac gating or peripheral-pulse gating.

FASE BB (Black Blood)
Used for chest imaging to acquire cardiac and thoracic images with reduced blood-flow artifacts. Applies a black-blood pre-pulse to suppress the signals from blood flowing into the slice plane.

Sequential FASE
Multislice imaging of the heart and great vessels, useful for the sequential acquisition of different slice images in the same cardiac phase.

TrueSSFP 2-D/3-D
- Rapidly obtains T2 or T1 contrast-weighted images.
- Suitable for imaging relatively longer T2 tissues and vascular structures during breath holds.
- Fat saturation is possible by dividing scans into multiple segments.

FSE/FASE T2 Plus
- Reduces scan times and increases resolution with no loss of T2 contrast and SNR by promoting transverse magnetization recovery in FSE and FSE 2-D.

FSE 3-D RealIR Head Imaging
Obtains heavily T1-weighted FSE 3-D images in a shorter time.

FE 3-D SSFP
Used in neuro and orthopedic applications to acquire images with T2/T1 contrast in a shorter time.

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m-Vox

- Allows isotropic, FSE, 3-D volume acquisitions, which can then be reformatted into multiple imaging planes to increase efficiency and reduce patient imaging time.
- Can be used with T2 and T2 FLAIR contrasts.

MNEURO PACKAGE FOR TITAN

MNEURO PACKAGE

- The mNeuro software package provides pulse sequences for diffusion imaging, perfusion imaging and fMRI (functional magnetic resonance imaging) as well as new imaging functions to expand the range of clinical applications.

Diffusion Imaging
Images can be acquired by enhancing diffusion water molecules in the body.

EPI Diffusion

- Isotropic diffusion-weighted images can be generated through calculations based on images acquired with MPG applied in the slice, readout or phase directions.
- Apparent diffusion coefficient images can be generated by calculation using two or more images acquired with different MPG levels. It is possible to specify this method before the start of the scan.

BODY VISION AND DTI PACKAGE FOR VANTAGE

DTI - Diffusion Tensor Imaging
Visualizes white-matter fibers running in a specific direction based on the diffusion anisotropy.

The following can be calculated based on the acquired images:

- Amount of diffusion in each direction
- Degree of anisotropy
- Sum of diffusion factors

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Requires at least seven sets of diffusion-weighted images:

- One set must be without MPG (motion probing gradient)
- At least six sets must be with the MPG pulses applied in different directions (with 6 directions possible).

The information generated from the diffusion gradients can be used to calculate directional vector, which can be used to describe the trajectory of molecular motion. The fiber direction is indicated by the tensor's main linear trajectory (lamba1, lamba2 and lamba3).

Post-Processing for Diffusion Tensor

- FA (Fraction Anisotropy) image shows the degree of diffusion anisotropy, and can be generated automatically after image acquisition.
- Lamba1, lamba2, lamba3 images (characteristic value images) are generated by converting these values from the diffusion tensor.

Perfusion Function (ASL)

Generates perfusion-weighted images without contrast by labeling the blood with the RF pulse and using it as a tracer to obtain vascular or perfusion-weighted images.

Captures images of flow components entering the slice by eliminating the stationary tissues. This is done by subtracting the tagged image, which includes the labeled flow, from the control image.

Functional Magnetic Resonance Imaging (fMRI)

Generates images of local areas in which the signal intensity increases when the patient is stimulated due to the BOLD and inflow effect.

Two series of images are acquired:

- When stimulation is applied to the patient
- When the patient is at rest

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No contrast is needed because:

- Hemoglobin is used as a native contrast medium
- Cerebral function information is assumed from the changes in signal intensity

Multishot FE EPI

- Single-shot EPI is modified by extending the ETS, which reduces the imaging time while ensuring the spatial resolution and SNR of a standard FE technique.
- The time required for T1 weighted-imaging of the abdomen is reduced while maintaining high-image contrast, spatial and temporal resolution.

High b value

- Increases the contrast in diffusion-weighted images.
- The permissible maximum b value is 10000.
- An extended sampling time is used to improve the image quality.

Diffusion for tissues with short T2

- SE_EPI sequences with 105ms TE or less is used for tissues with short T2.
- Two types of MPG pulse application methods are available:
  - 3-Axis
  - Tensor
- DTI license is required for the Tensor method.

Fat suppression

Three types of fat suppression methods are available:

- PASTA
- FatSAT (recommended for DWI of the head)
- IR

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SPEEDER
Parallel imaging can be used with EPI to reduce distortion.

T1 weighted imaging for the abdomen

- Use the 3-DFT-EPI technique for higher data acquisition efficiency by increasing the number of phases for dynamic scanning or for reducing breath-hold time.
- The 3-DFT technique achieves resolution in the slice direction as high as 1mm.

V-TRACE (Variable True Rate Angiography with Combined Encodings)
This head-imaging application acquires four image contrasts in one sequence, visualizing slow- and fast-velocity vessels together. V-TRACE is especially effective for visualizing collateral vessels, which are difficult to see with standard TOF imaging.

Combines the advantages of TOF and FSBB to produce MRA images that depict blood vessels with a wide range of flow velocities, making it ideal for head imaging.

This dual-echo 3-D FE sequence generates high-intensity vascular images in a scan time nearly equivalent to only TOF or FSBB.

- First echo acquired using standard TOF
- Second echo acquired using flow-sensitive black blood (FSBB) technique
- Echoes are combined using one of two subtraction methods:
  - Simple weighted subtraction (SWS) for thin slabs in the axial plane
  - Frequency weighted subtraction (FWS) for thick slabs in any plane
- Pulse sequence type: FE3-D_hop
- Main contrast types:
  - 3-D TOF
  - FSBB
  - T1W
  - Combined 3-D TOF and FSBB

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- Scanning plane:
  - Axial
  - Coronal
  - Sagittal

V-TRACE does not employ an STC pulse for background suppression, therefore, the SAR does not increase, and the original TOF image can be used as a T1W 3-D image.

DIFFUSION TENSOR TRACTOGRAPHY APPLICATION

This application creates various types of diffusion maps and allows visualization of multiple white matter tracts based on the diffusion tensor imaging data.

- Isotropic DWI
- Isotropic ADC
- Mean B0
- ColorMap 1/2/3
- Lambda 1/2/3

GATING-W/T.100 GATING PACKAGE -- WIRELESS

WIRELESS CARDIAC GATING UNIT

Performs wireless ECG gating for cardiovascular MR examinations that require gating.

WIRELESS PERIPHERAL / RESPIRATORY GATING PACKAGE

Performs wireless peripheral and respiratory gating for cardiovascular, MRA and body MR examinations that require gating.

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DICOM STORAGE COMMITMENT KIT

Guarantees the receiver that another device has taken ownership of the images sent.

- Identifies that images have been sent to a destination
- Stores selected images on a DICOM-compliant server
- Obtains commitment to retain the images

Note: This is a single user license. A separate license must be ordered for each console.

DICOM Q/R SCP UNIT

Query and retrieve image data on the MR console from a network image server, such as PACS.

Note: This is a single user license. A separate license must be ordered for each console.

VIDEO FADER

CONSOLE DESK 65" X 36" X 30"

Measures 65" x 36" x 30"

SILENT SCAN STEREO AND INTERCOM SYSTEM

Includes the following:

Patient Microphone
Patient's headset has a built-in microphone for crystal-clear communication between technologist and patient. Coupled with Pianissimo technology, the patient will be heard, regardless of scan type or location within the MRI bore.

Patient Alarm System
A hand-held, rubber squeeze bulb for claustrophobic patients to trigger an audible alarm at the communication console.

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Communication Console
Includes a flexible, gooseneck microphone for effortless patient communication.

Patient Comfort Music Headset
Offers hearing protection and allows patients to relax to music, free from gradient noise. Careful matching of transducer characteristics and filter design provides remarkably clear music.

LCD MONITOR FOR ECG

ELECTRODE PADS (BOX OF 25) (Qty 2)

PATIENT PADS FOR SPINE AND EXTREMITY

OVERHEAD CABLE INSTALLATION

Allows for overhead cable installation during scanner installation.

GANTRY LIGHTING OPTION

The ambient gantry lighting kit provides a soothing blue glow on the front cover of the magnet. Patients who see a bright friendly scanner will ultimately respond more positively and tolerate the scanning process more effectively.

VRDU-TITAN-U4-H TEAL VRDU FOR TITAN U4, 480V

The TEAL voltage regulator (VRDU) is a highly reliable, dual-conversion power conditioner. It is designed to address the vast majority of common power problems found in an imaging environment, thus providing clean regulated power and good grounding for optimal reliability and performance of MRI systems.

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Power Conditioning

The VRDU contains a shielded, ultra-low impedance isolation transformer coupled with filtering and surge suppression to make a complete power conditioning package. The quality of power to the Toshiba MRI system is improved in many ways:

- The isolation transformer re-references the power line to the local ground point (with connection to local building steel), isolating the system from upstream, ground-quality problems.
- The transformer shield helps protect against ground impulses and noise ("common mode" disturbances).
- The sine wave tracking filter protects against both high-frequency noise and fast-voltage impulses ("normal mode" disturbances), clamping spikes and filling in notches.
- The surge suppressors protect against slower voltage impulses that have frequency below the filter cutoff.

Voltage Conversion

Wiring costs are significantly reduced since the VRDU accepts a single, 480V delta input with code minimum ground, supplying 115/200V, 3-phase WYE to the transformer cabinet and 230/400V, 3-phase WYE to the generator cabinet.

Distribution

The VRDU comes prepackaged with distribution circuit breakers needed for the Gradient and Transformer Cabinets.

Control

The VRDU includes a circuit breaker on the input (primary) control signal for remote, emergency off control of the circuit breaker.

Impedance Control

The ultra-low impedance design of the isolation transformer helps ensure the power feed meets the low impedance requirement of today's MRI labs as spelled out in the Toshiba Optimal Power Specifications (TOPS) manuals.

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Approvals
UL listing will reduce time and uncertainties in obtaining local electrical inspection approvals.

PACT78S3-T4-ZTM.001 **DRAKE HEAT EXCHANGER DUAL LOOP 460 FOR TITAN OR ATLAS Z**

The Drake Dual Loop Chiller is composed of a base unit and the Indoor Heat Exchanger. The Indoor Heat Exchanger is supplied as standard equipment and is placed in the MRI equipment room. The base unit (chiller) is installed on the outside of the building, typically on a concrete pad. Advantages include ease of installation and a smaller footprint in the MRI equipment room. The chiller comes with a remote monitor that provides remote indications of chiller operation.

Note: The PACT78S3-T3-ZTM 208 Vac and PACT78S3-T4-ZTM 460 Vac chillers are designed to operate in ambient temperatures of -20F to 125° F.

MZPT-1510/S3 **TITAN HIGH CAPACITY TABLE - FACTORY OPTION**

This option increases the weight limit of the standard Titan table from 440 lbs. to 550 lbs. It allows travel in all directions.

Note: This option is not compatible with the Extended Travel option.

MJAJ-197A/J1 **4-CHANNEL FLEX SPEEDER COIL**

This versatile, 4 element coil's flexible design allows it to wrap around extremities, joints and a variety of other anatomical areas the user wishes to image.

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MJAJ-227A/S1	16-CHANNEL FLEX SPEEDER LARGE COIL

The large 16-element flexible coil is designed to be lightweight and easy to position for multiple clinical applications. The coil:

- Easily wraps around extremities, joints and a variety of other anatomical areas the user wishes to image
- Lies flat for long bone studies
- Combines with other integrated coils to create a posterior and anterior array for maximum contrast and spatial resolution
- Has a pre-amplifier located on it, so there's no extra box to deal with when positioning the coil on the patient

Note: On an 8-channel RF system this coil operates as an 8-element coil.

Prerequisite: This coil will only work with the 1.5T Titan with software at or above 2.20.

MJCA-207A/S1	FLEX COIL POSITIONING PAD SET

The Flex Coil Positioning Pad Set contains positioning accessories for ankle, knee, elbow and other clinical applications. The pad set will facilitate in positioning the coil easily and reliably for optimal image quality.

MBREAST-T.100	MBREAST PACKAGE
	SOFTWARE, MBREAST
4000235-11-12	RADIANCE PLUS BREAST IMAGING PACKAGE FOR TITAN

The RADIANCE Plus Breast Imaging Package is an all inclusive package that includes specialized sequences and the Sentinelle Breast SPEEDER Coil. This coil is an 8-channel coil specially designed for high-resolution imaging of the breasts and axillary tissues. This coil is SPEEDER compatible, can be used in unilateral and bilateral exams, and allows the Vantage Body Coil to be used at any time while the coil is in the scanner to accommodate for large FOV body coil localizers.

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Compatibility

- 1.5T Vantage Titan

Interventional Access

- Variable Coil Geometry
- Lateral approach accessibility for biopsy:
  - 70 cm and 60 cm bore: 352.71 cm^2
- Medial approach accessibility for biopsy:
  - 70 cm and 60 cm bore: 276.82 cm^2
- Bilateral intervention capable

Patient Accommodation

- Volume per breast (70 cm bore): 8287 cc
- Volume per breast (60 cm bore): 6672 cc
- Distance from sternum to bore (70 cm bore, Titan): 35 cm
- Distance from sternum to bore (60 cm bore, Atlas): 30 cm
- Arms at side, arms back or arms forward positioning
- Adjustable head rest
- Patient pads: 9 with memory foam
- Patient weight up to 200kg

Training

- 6.0 Category A Continuing Education Hours with initial applications training on imaging and intervention. This applications training is provided by Sentinelle Medical Imaging.

Techniques included in this package:

- Quick 3-D's for dynamic evaluation
- Enhanced Fat saturation
- Silicone saturation

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- High resolution axial and sagittal sequences
- Unique slice selective fat saturation
- LFOV imaging
- SPEEDER compatible

Note:
Warranty / Service
Customer hereby acknowledges and agrees that solely as a convenience to Customer, Toshiba is entering into an agreement with Sentinelle, ("Vendor") in order for such Vendor to sell, deliver, install, and service its products, and perform other work to and for the benefit of Customer. However, Customer hereby agrees that Toshiba will not be liable for any defects in design, material and workmanship in the products or services sold and/or performed by Vendor or otherwise be responsible for such products or services. Customer will have no rights or remedies against Toshiba for such products or services. Customer's sole remedy will be against Vendor. Additional warranty may be purchased directly from Sentinelle ("Vendor") after the initial 12 month warranty period has expired.

Prerequisite: V9.5 Software

MR-TRAINING-99 MR BREAST IMAGING COURSE - IRVINE

This 2-day training course is held at Toshiba's Education Center in Irvine, CA for one technologist that provides a foundation of breast anatomy and physiology, patient prep & positioning and parameter selection. Advanced concepts include an overview of the ACR guidelines for breast MRI, evaluation of breast cancer, implant rupture and the use of CAD. After completing this program, the technologist will be proficient in the following applications and operations: Breast anatomy, physiology & disease process, scanning of patients for breast cancer and implant rupture and image processing.

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The following expenses are included:

- Domestic coach round trip airfare to Irvine, California
- Lodging for three nights
- Transportation to and from the course daily
- Breakfast, lunch and dinner meals provided during training
- Tuition (all inclusive) for $3,000.00

MJAH-167A.100 OCTAVE HEAD SPEEDER COIL KIT

OCTAVE HEAD SPEEDER COIL

Combined head/neck coil has up to 11 elements, making it ideal for head, neck and neurovascular studies.

- This array coil is part of the Octave integrated coil design and can be used in combination with the Octave spine and body coils.
- Advanced coil technology permits the use of up to 11 coil elements for excellent coverage as well as high signal-to-noise ratio.
- Head coil base has seven elements enabling image acquisition without the anterior attachment for the most claustrophobic patients.
- Tiltable up to 15 degrees to accommodate kyphotic patients.

TILTABLE OCTAVE HEAD COIL BASE

MJAJ-177A/S1 SHOULDER SPEEDER COIL

High Resolution, SPEEDER compatible, 6 Element Array coil. The unique design incorporates flexible coil elements both posterior and anterior which provides excellent deep tissue visualization of the shoulder joint anatomy. The design also allows for use on patients of all sizes and easily switches for right or left shoulder scanning applications. Pads, securing strap and Operator's Manual are included.

Prerequisite: v9.51 Software

QUOTATION/ORDER ORDER DETAIL

DATE: 9/25/2014

SID NO: 30012104
QUOTE NO: 57064-6

PRESENTED TO:

SYCAMORE SHOALS HOSPITAL
1501 W ELK AVE
ELIZABETHTON, TN. 37643

MJAS-147A/E1 — **ATLAS SPINE COIL**

Feet-first positioning maximizes patient comfort and increases flexibility with this moveable, 32-element array suitable for spine studies with optimal signal-to-noise ratio. This coil is integrated into the patient table and can remain on the table for most exams.

- Coil covers 100 cm and can be positioned at either end of the table.
- Works with the Atlas body coils to form the posterior elements of the array. Together the spine and body coils can be used for imaging the spine, abdomen, pelvis and lower extremities.

MBPS-1503/S1 — **RAPID TRANSPORT SYSTEM - RIGHT**

Toshiba's unique rapid transport system provides a complete, MR compatible, patient transport system that does not disable the scanner when it is removed. This system allows the gurney to transport the patient from room to imaging suite, dock on top of the Titan's table and then be moved in the scanner for imaging. When the patient is done, the table comes out and lowers the top back onto the gurney for transport back to the patient's room. The scanner is still capable of imaging while this occurs as the MR table has not been removed.

Prerequisite: Requires V2.21 or later Software on the 3T
Requires V2.2 or later Software on the 1.5T

WSAE-HW-0002.100 — **AEGIS CAD WORKSTATION SINGLE USER**

The Aegis™ Breast post processing software is a dedicated application for MR image analysis. It offers a full range of functionality that will enhance MR imaging and functionality. The 3-D breast software package will add the necessary post processing tools needed to analyze and display complex MR breast exam images as well as display of other associated DICOM images.

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The software is supplied with a high performance desktop workstation. Optional Prostate Analysis 1.0 software tools are available for prostate evaluation and color maps.

Key software functionality includes:

Optimized speed
- Fast time to first image
- Real-time 3-D rendering (MIP, Solid, MPR)
- Automated loading of viewports through hanging protocols
- Single click lesion highlighting for 2-D or 3-D rendering

Optimized control
- Configurable site and radiologist settings
- Dynamic control of 3-D visualization (3-D + time)
- 3-D image location tools such as Reference Lines and Spatial Locator
- Lesion-centric mode for improved morphological viewing
- Advanced optical flow-based 3-D motion correction
- Breast comparison tool for sagittal imaging

Optimized ease of use
- Automated multiple time point kinetic analyses and graphing
- Familiar PACS-like viewing functionality such as hanging protocols
- Configurable automated pre-processing of motion correction
- Reports appended to patient DICOM study

Optimized biopsy guidance
- Automatic registration of Sentinelle biopsy grids through specialized embedded fiducial markers
- Automated display of biopsy grid and plug position
- Interventional images are automatically reoriented as a function of breast approach to be aligned with the radiologist's viewpoint for intuitive navigation.

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- A specialized clock face tool helps the user orient towards the selected target.
- Sentinelle Aegis™ Breast supports all major vacuum assisted biopsy devices.

HARDWARE

- 1 x Desktop Workstation
- Quad Core Intel Processor or later
- nVidia Quadro GeForce GTX 285 or later
- 300 GB Solid State Hard Drive
- 16 GB RAM
- Windows 7 Professional 64-bit
- Resource Recovery CDs with Diagnostic Utilities and Drivers
- USB Keyboard
- USB Optical Mouse with Scroll Wheel
- DVD RW
- Aegis™ Breast, NET 3.5 SP1 and Adobe Reader

Note: Specs are for reference only and are subject to change.

Warranty / Service
Customer hereby acknowledges and agrees that solely as a convenience to Customer, Toshiba is entering into an agreement with Sentinelle ("Vendor") in order for such Vendor to sell, deliver, install, and service its products, and perform other work to and for the benefit of Customer. However, Customer hereby agrees that Toshiba will not be liable for any defects in design, material and workmanship in the products or services sold and/or performed by Vendor or otherwise be responsible for such products or services. Customer will have no rights or remedies against Toshiba for such products or services. Customer's sole remedy will be against Vendor. This product comes with a 1 year warranty from the vendor.

AEGIS CAD WORKSTATION SINGLE USER

AEGIS BASE (MM) PLATFORM

AEGIS BASE LICENSE

TOSHIBA
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TOSHIBA AMERICA MEDICAL SYSTEMS, INC.

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AEGIS BREAST LICENSE

AEGIS BREAST PLUG-IN

DELL 27" COLOR DISPLAY

AEGIS LAPTOP COMPUTER (BIOPSY ONLY)

AEGIS BREAST BIOPSY LICENSE

TOSHIBA
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TOSHIBA AMERICA MEDICAL SYSTEMS, INC.

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ADDENDUM

ALL INFORMATION CONTAINED IN THIS QUOTATION IS CONFIDENTIAL AND MAY NOT BE DISCLOSED TO ANY THIRD PARTY WITHOUT TOSHIBA'S PRIOR WRITTEN CONSENT.

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PRODUCT WARRANTY AND SERVICES COVERAGE

SYSTEM WARRANTY TERMS

Toshiba America Medical Systems, Inc. (TAMS) warrants to Customer that the product(s) to be delivered hereunder will be free from defects in material, manufacturing workmanship, and title. Any product or part furnished to Customer during the warranty period (stated in the table below) to correct a warranty failure shall be warranted to the extent of the unexpired term of the warranty applicable to the repaired or replaced product or part.

The warranty period shall commence on the date the Product is delivered to Customer. However, if TAMS installs the product, the warranty period for such product shall commence on the date the installation of the product is complete. Notwithstanding the foregoing, in the event that the installation of the product is delayed for a total of thirty (30) days or more from the date of delivery for any reason or reasons for which TAMS is not responsible, the warranty period for such product may, at TAMS' option, commence on the thirtieth (30th) day from the date such product is delivered to Customer.

WARRANTY EXCLUSIONS

Warranty coverage does not include any defect which results, in whole or in part, from (1) negligent storage or handling of the product by Customer, its employees, agents, or contractors, (2) failure of Customer to prepare the site or provide power requirements or operating environmental conditions in compliance with any applicable instructions or recommendations of TAMS, (3) absence of any product, component, or accessory recommended by TAMS but omitted at Customer's direction, (4) any design, specification or instruction furnished by Customer, its employees, agents, or contractors, (5) any alteration of the product by persons other than TAMS, (6) combining TAMS' product with any product furnished by others, (7) combining incompatible products of TAMS, (8) improper use of the product, improper maintenance of the product by a party other than TAMS, or failure to comply with any applicable instructions or recommendations of TAMS, or (9) acts of God, acts of civil or military authority, fires, floods, strikes or other labor disturbances, war, riot, or other causes beyond the reasonable control of TAMS.

TAMS does not warrant any products not manufactured by Toshiba such as, without limitation, monitors, cameras, computer equipment, etc. Such items will be furnished subject only to the manufacturer's warranty, if any, and without any warranty whatsoever by Toshiba.

Warranty coverage also excludes consumables, including but not limited to cassettes, magazines, imaging screens, disks, cartridges, etc.

GLASSWARE WARRANTY

Glassware, including X-ray tubes and Image Intensifiers, are provided separate warranties. Glassware included with the purchase of a new system is governed by the glassware warranty, described below, not the system warranty.

CT X-ray tubes carry a prorated warranty based on the number of rotations shown below or 12 months, whichever comes first.

Tube Type	Prorated Warranty
CXB-750/D/4A:AQ/RXL,AQ/LB-SERIES, ASSUREPLUS-V, AQ64, AQ16, AQ8	200,000 rotations*
CXB-750/E/2A:AQ/ONE/ASSURE	150,000 rotations*
CXB-750/F/2A:ONE-320-SERIES-V,ONE-640-SERIES-V, ONE-VISION-SERIES-V	100,000 rotations*
CXB-750G/2A: PRIME-SERIES	200,000 rotations*

*A rotation is any 360-degree or single rotation of the gantry with X-rays on.

The following time-based warranty terms apply to all other glassware:

Tube Type	Time-Based Warranty
Liquid Bearing Tubes (DSRX-TXXXX)	12 months, non-prorated
All Other X-ray tubes	12 months, non-prorated
Image Intensifiers	18 months, non-prorated

GLASSWARE PRORATION CALCULATION:

Credits for glassware that fails during the warranty periods stated above will be calculated as follows:

Tubes with Prorated Rotation Warranty:

$$\text{Credit} = 1 - \frac{\text{Number of Rotations Used}}{\text{Number of Rotations Warranted}}$$

Credit will be applied to the purchase of the replacement X-ray tube or Image Intensifier. Complete glassware coverage during warranty period may be purchased from the local services organization at an additional charge.

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Tubes with Non-Prorated, Time-Based Warranty:

Tubes with a non-prorated warranty will be replaced during the initial warranty period at no charge to the customer. The replacement tube carries the remainder of the original warranty. For example, a tube with a 24-month non-prorated warranty fails at month thirteen (13), the tube is replaced at no charge and carries eleven (11) months of warranty.

REMEDIES
If TAMS determines that any product fails to meet any warranty during the applicable warranty period, TAMS shall correct any such failure by either, at its option, repairing, adjusting, or replacing without charge to Customer any defective or nonconforming parts of the product. TAMS shall have the option to furnish either new or remanufactured replacement parts or assemblies. During the warranty period, Toshiba will furnish free of charge any upgrades, including software required to correct any defect in the warranted products or as required under applicable laws.

WARRANTY SERVICE
Warranty service during the applicable warranty period will be performed without charge to Customer during TAMS' normal business hours, Monday through Friday, excluding holidays. Subject to the availability of personnel, after-hours service is available upon request at an additional charge.

The remedies set forth herein are conditional upon Customer promptly notifying TAMS within the applicable warranty period of any defect or nonconformance and making the product available for correction.

DISCLAIMERS AND LIMITATIONS ON LIABILITY
TAMS' obligation to repair or replace defective parts will be Customer's sole and exclusive remedy for a breach of the warranty set forth above. SUCH WARRANTY WILL BE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

In no event shall TAMS be liable for special, incidental or consequential damages. Toshiba does not warrant that the operation of the warranted products will be uninterrupted.

WARRANTIES BY PRODUCT LINE

	COMPUTERIZED TOMOGRAPHY	MAGNETIC RESONANCE	PACS SYSTEMS	ULTRASOUND	X-RAY VASCULAR	X-RAY R/F & RAD
SYSTEMS AND MAJOR COMPONENTS	12 Months	12 Months	12 Months	12 Months	12 Months	12 Months
ACCESSORY OPTIONS	6 Months	6 Months	6 Months	6 Months	6 Months	6 Months
REPLACEMENT & OPTIONAL PARTS	90 Days	90 Days	90 Days	90 Days	90 Days	90 Days
UPGRADE COMPONENTS	90 Days	90 Days	N/A	12 Months	6 Months	6 Months
MISC. WARRANTY ITEMS	Detectors: Solid State 12 Months	N/A	N/A	Transducers: 12 Months	N/A	N/A

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TERMS AND CONDITIONS OF SALE

1. GENERAL TERMS. Unless otherwise specified on the face of this document, this Quotation/Order ("Agreement") will remain valid only if accepted by Customer no later than 60 days from date of submission to Customer.

2. TITLE AND RISK OF LOSS. Title and risk of loss to the Equipment purchased under this Agreement will pass to Customer: (a) if Toshiba is to provide installation, upon Toshiba's completion of installation, or (b) if Toshiba will not provide installation, upon delivery by Toshiba to a common carrier at Toshiba's facility from which the Equipment is shipped.

3. TERMS OF PAYMENT. Prices stated are F.O.B. Customer's facility. All taxes which are payable by Toshiba in connection with the sale, use, or possession of the Equipment (excluding income taxes), will be paid by Customer in addition to the quoted price. Terms of payment for, C.T., M.R.I, X-Ray, and the McKesson System will be cash-10% upon execution of this Agreement, 70% upon delivery, balance due upon completion of installation and/or availability for first use, whichever is earlier. Terms of payment for Ultrasound will be cash-10% upon execution of this Agreement, 90% NET upon completion of installation and/or availability for first use, whichever is earlier. All invoices paid after due date will be assessed a late payment charge of the lesser of 1 1/2% per month or the maximum rate permitted by law.

4. DELAYS. If Customer changes the scheduled delivery date specified on the face of this document ("Scheduled Delivery Date") during the period of 120 days preceding such date, Customer will nevertheless pay the installment of the purchase price which would have been payable upon delivery, on the Scheduled Delivery Date as if delivery had been made on such date. In addition, Customer will pay all extra costs incurred by Toshiba as a result of such delay, including, without limitation, storage and transportation. Storage fees will be charged at commercially comparable rates for storage on Toshiba's site. If delivery is delayed by 12 months or more from the Scheduled Delivery Date, except through the fault of Toshiba, the price set forth in this Agreement may be increased by Toshiba to a level equal to the prevailing price in effect at the time of the revised delivery date.

5. ACCEPTANCE BY TOSHIBA. This Quotation/Order will not be binding on Toshiba even if signed by a Toshiba employee, until Customer's order for the Equipment is booked by Toshiba's Headquarter office.

6. EQUIPMENT INSTALLATION. Toshiba will install all Equipment purchased under this Agreement and connect them to existing power and/or plumbing lines at no additional charge to Customer. Customer will be responsible for electrical wiring, plumbing, carpentry, plastering, painting, or all other site preparation required prior to installation and connection of the Equipment by Toshiba. Customer will provide space at the installation site for the safe storage of Toshiba's tools, test equipment and other materials used for installation at no charge to Toshiba. Customer shall, at its cost, obtain all permits and licenses required by governmental authorities in connection with the installation and operation of the Equipment. The Equipment may contain certain components, which may have been re-manufactured. However, such components will meet the manufacturer's specifications for new components as of the date of completion of installation. Customer acknowledges that the System and Software are designed to operate within certain power, temperature, airborne contamination, and humidity ranges. Customer will be responsible for, without limitation: (i) preparing and maintaining the Customer facility in conformance with the Site Preparation Guide; (ii) maintaining its network infrastructure; (iii) providing Toshiba, McKesson or its subcontractors access to a network connection in or near the area of the System being serviced by the equipment service staff; and (iv) supplying computer grade AC power. The Equipment relies upon a stable grounded connection to the main power grid in order to function effectively. Customer acknowledges that AC power supply quality may be a problem in old facilities or in those facilities receiving poor quality utility service and that power conditioning may be necessary in such cases.

7. EQUIPMENT OPERATION. Customer agrees that all Equipment purchased under this Agreement will be operated exclusively by duly qualified technicians and/or medical doctors in a safe and reasonable manner in accordance with Toshiba's written instructions, applicable laws and regulations, and for the purposes for which such Equipment was intended.

8. LIMITED WARRANTY AND REMEDY. **A. For the Toshiba Equipment:** For the warranty period described below by product, Toshiba, as its only obligation, will replace or repair, without charge to Customer during Toshiba's normal working hours (if Customer requests warranty service outside such hours, Customer will pay overtime premium for labor), any component of the Equipment that is defective in materials or workmanship, provided such defect is reported to Toshiba within the warranty period. Toshiba's warranty

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period is as follows: (a) Systems and Major Components - one year from date of completion of installation; (b) Accessories/Options (except glassware) - six months from date of completion of installation. Components not manufactured by Toshiba will be furnished subject only to the manufacturer's warranty, if any, and without any warranty whatsoever by Toshiba. During the warranty period, Toshiba will furnish free of charge any upgrades, including software required to correct any defect in the Equipment or as required under applicable laws.

B. For the McKesson System: The McKesson System ("System") will be covered by a 12-month warranty beginning the date of completion of installation of the System (the "Warranty Period"). The warranty covers repair of any defects in materials or workmanship related to the computer equipment ("Equipment") that is included in the System purchased by Customer under this Agreement. The warranty also covers correction of any McKesson software ("Software") that does not conform with its functional specifications. In order to receive services during the Warranty Period, Customer must provide McKesson and Toshiba with remote access through a VPN. During the Warranty Period, Customer is entitled to (a) all Generally Available Software Updates except for Updates that are separately priced and marketed by Toshiba or McKesson, and (b) all Generally Available Software Upgrades, except for Upgrades that are separately priced and marketed by Toshiba or McKesson. *"Software Updates"* means Software modifications, enhancements, corrections, improvements, and patches to the existing functionality of Customer's licensed version of the McKesson Software (e.g., version 4.1 to 4.3 to 4.5). *"Software Upgrades"* means new versions and future releases of the McKesson Software (e.g. version 4.x, 5.x, 6.x). Software Updates or Upgrades that provide new features not originally purchased may be separately priced and marketed. Software Updates and Software Upgrades to the McKesson Software will be delivered remotely, on-line. The warranty does not include any non-McKesson Software, the labor and travel expenses associated with on-site installation of a Software, or any hardware addition or modification.

The warranty set forth in this Section will not apply:

a. if Customer operates the Software on equipment other than Equipment purchased from Toshiba or attaches other equipment to the System not approved by Toshiba;
b. if a person or entity other than McKesson or its authorized third party suppliers modifies the Software;
c. as a result of Customer's improper use, abuse, neglect of the Equipment, including failure to maintain environmental conditions within the operating range specified by the Equipment manufacturer or accident;
d. as a result of viruses or other corruption caused by external entities; or
e. for damages resulting from a Force Majeure condition described in Section 13 below.

C. The Following Applies to Both the Toshiba Equipment and the McKesson System: Toshiba does not warrant that the operation of the Equipment of the System will be uninterrupted. All defective parts replaced by Toshiba will become the property of Toshiba. Replacement parts may be re-manufactured. However, such parts will meet the manufacturer's specifications for new components as of the date of completion of installation. TOSHIBA'S OBLIGATION TO REPAIR OR REPLACE DEFECTIVE PARTS OR SOFTWARE WILL BE CUSTOMER'S SOLE AND EXCLUSIVE REMEDY FOR A BREACH OF THE WARRANTY SET FORTH IN THIS AGREEMENT. SUCH WARRANTY WILL BE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. The warranty set forth in this Agreement will not apply to, and Toshiba will not be liable for any defects resulting from misuse, repairs performed by unauthorized third parties, accidents, acts of God, or neglect of anyone other than Toshiba.

9. LIMITATION OF LIABILITY. NEITHER TOSHIBA NOR CUSTOMER WILL UNDER ANY CIRCUMSTANCES BE LIABLE FOR CONSEQUENTIAL, SPECIAL, INCIDENTAL, OR EXEMPLARY DAMAGES OR ECONOMIC LOSS ARISING OUT OF OR RELATED TO THE TRANSACTIONS CONTEMPLATED IN THIS AGREEMENT, EVEN IF EITHER PARTY IS APPRISED OF THE LIKELIHOOD OF SUCH DAMAGES OCCURRING. IN NO EVENT WILL EITHER PARTY'S LIABILITY TO THE OTHER (WHETHER BASED ON AN ACTION OR CLAIM IN CONTRACT, TORT, INCLUDING NEGLIGENCE, STRICT LIABILITY, OR OTHERWISE) ARISING OUT OF OR RELATING TO THE TRANSACTIONS CONTEMPLATED IN THIS AGREEMENT EXCEED THE AGGREGATE AMOUNT ACTUALLY PAID BY CUSTOMER TO TOSHIBA UNDER THIS AGREEMENT. THE LIMITATION OF LIABILITY SET FORTH ABOVE WILL NOT APPLY TO CLAIMS FOR PERSONAL INJURY OR PROPERTY DAMAGE CAUSED BY EQUIPMENT DEFECTS, OR TO CLAIMS FOR PATENT INFRINGEMENT.

10. SECURITY INTEREST. Toshiba hereby reserves and Customer grants to Toshiba a security interest pursuant to the Uniform Commercial Code, in and to the Equipment (and all products and proceeds of it) until full payment of the purchase price is received.

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In the event that Customer finances its acquisition of the Equipment through a lease, conditional sale contract, secured loan agreement or other financing agreement (collectively, "Lease") with Toshiba, then the security interest in the Equipment (and all products and proceeds thereof) shall secure all obligations of Customer due and to become due under the Lease.

11. REMOVAL OF EQUIPMENT. Until Toshiba has received full payment of the purchase price, Customer will not remove all or any part of the Equipment from Customer's premises, nor will Customer sell, lease, transfer or otherwise part with the possession of, or permit any lien or encumbrance to be placed on all or any part of the Equipment.

12. REMEDIES OF TOSHIBA. If Customer fails to make any payment when due under this Agreement or under any other agreement between Customer and Toshiba, or becomes insolvent or makes an assignment for the benefit of creditors, or if a petition in Bankruptcy is filed by or against Customer, or if the financial responsibility of Customer becomes impaired or unsatisfactory in Toshiba's reasonable judgment, or if Customer otherwise breaches any of the terms and conditions of this Agreement, then Toshiba may, without prior notice or demand, defer shipments, cancel the balance of the order, suspend performance of any obligation (including without limitation, all obligations set forth under Limited Warranty And Remedy above), and/or take immediate possession of the Equipment delivered, until the full purchase price of the Equipment is paid by Customer or, at Toshiba's discretion, until security satisfactory to Toshiba is given by Customer. Any costs incurred by Toshiba as a result of suspending performance or repossession or collection will be payable by Customer. Toshiba may sell repossessed Equipment with proceeds to be applied to unpaid balance and expenses incurred in sale, repossession and collection. Customer will pay any remaining deficiency. Toshiba may exercise any other rights available to it by law.

13. EXCUSED PERFORMANCES. Neither party will be liable to the other for non-performance or delay in performance resulting directly or indirectly from any occurrences beyond such party's control, including without limitation, strikes or other labor troubles, acts of God, war, accidents, fires, floods, other catastrophes, inclement weather, transportation, unavailability of materials and labor, delays caused by suppliers, or laws, regulations, or acts of any governmental agency.

14. SOFTWARE. All rights and interest in any software that may be furnished under this Agreement, and any updates and enhancements to it, will remain the property of Toshiba. Such software is being furnished to Customer under a non-exclusive license. Customer will not, or allow others to decompile, modify, copy, reproduce, or transcribe the software nor allow third parties to use the same without Toshiba's prior written consent. Upon Toshiba's request, Customer will execute an End-User Software License Contract, in a form to be mutually agreed between the parties.

15. CANCELLATION. Customer may not cancel the order subject to this Agreement except with Toshiba's prior written consent. In the event of such cancellation, Toshiba will be entitled to recover any and all damages suffered by it caused by the cancellation as allowed by law, but in no event less than an amount equal to twenty percent (20%) of the purchase price for a restocking charge.

16. ASSIGNMENT. Neither party may assign any of its obligations under this Agreement without the prior written consent of the other party However, some of the obligations stated in this Agreement, such as the ones relating to installation of the McKesson System and warranty may be performed by Toshiba's contractors or suppliers.

17. EXPORT REGULATIONS. This Agreement involves products, and/or technical data that may be controlled under the U.S. Export Administration Regulations and may be subject to the approval of the U.S. Department of Commerce prior to export. Any export or re-export by Customer, directly or indirectly, in contravention of such Regulations is prohibited.

18. ATTORNEY'S FEES AND COSTS. In the event of any legal proceeding involving any party to this Agreement against the other relating to the subject matter of this Agreement, the prevailing party in such proceeding will be entitled to recover attorney's fees, expert fees, and court costs against the non-prevailing party.

19. ENTIRE AGREEMENT. This quotation as well as the attached McKesson Pass Through Terms and Conditions contains the entire agreement between the parties and supersedes all prior and contemporaneous agreements between the parties, whether oral or written, relating to its subject matter, including, without limitation, all different or additional terms and conditions which may be contained in Customer's bid documents, purchase order or any other documents furnished by Customer. The provisions of this Agreement may not be modified unless in writing and executed by both parties.

SUPPLEMENTAL- 1

DRAKE REFRIGERATION INC.

May 28, 2015

EQUIPMENT PROPOSAL AND QUOTATION

QUOTE# 57064/30012104

Date of Quote:	Contact:	Phone#	Fax#
9/25/2014	Sycamore Shoals Hospital		

QUOTE SUBMITTED TO:
Toshiba America Medical Systems MRI Customer

JOB SPECIFICATIONS

Condensing Method:	AIR COOLED
Application:	MRI COOLING
Design Ambient / Water: (° F)	120
Entering Fluid Temp: (° F)	77.9
Leaving Fluid Temp: (° F)	65
Type Of Fluid To Circulate:	DISTILLED WATER
Fluid Flow Rate (GPM):	15 @ 72PSI
Voltage / Phase / Cycle:	208-230 / 3 / 60 or 460 / 3 / 60
BTUH Required:	90,000

NOTES

TAMS Atlas Z and Titan
R-407C
REFRIGERANT

Available 208/230V or 460V
Voltage needs to be specified on the chiller release form completed by the site contractor, and faxed to Drake to schedule the chiller shipment.

QUANTITY	MODEL - DESCRIPTION OF EQUIPMENT	LIST PRICE
1	PACT78S3	$ 26,347.00
1	ADDITIONAL 4 YEAR COMPRESSOR WARRANTY	INCLUDED
1	2HP S.S. SYSTEM PUMP 15GPM @ 72PSI	INCLUDED
1	DRAKE "CHILLERGUARD" INTERNET INTERFACE DEVICE	INCLUDED
1	MICROPROCESSOR CONTROLLER INCLUDING:	INCLUDED
	LOW FLOW INDICATOR	
	COMPRESSOR RUN INDICATOR	
	POWER ON AND FAULT INDICATOR	
	HIGH TEMP INDICATOR	
	WATER TEMP FREEZE THERMOSTAT	
1	D500-803 FAN CYCLE CONTROL	INCLUDED
1	D500-405 TANK LOW LEVEL INDICATOR	INCLUDED
1	SPARE FUSE HOLDER	INCLUDED
1	D500-201 TANK SIGHT GLASS	INCLUDED
1	D500-843 REMOTE INDICATOR PANEL	INCLUDED
1	D503-104H HEATED RECEIVER / HEAD PRESSURE	INCLUDED
1	D500-866 INDOOR HEAT EXCHANGER / PUMP WITH 12 GALLON STAINLESS TANK, SIGHT GLASS, GROUNDED ANODE & DRAIN VALVE	INCLUDED
1	5 GALLON BUCKET & CHILLER TANK FILL PUMP	INCLUDED
2	55 GAL DRUM PRE MIX 40% P. GLYCOL / WATER	INCLUDED
1	START UP/6MO PM/ 1 YEAR LIMITED WARRANTY (See details), Freight included (Continental US)	$ 4,500.00
	The price for the chiller is already included in the Toshiba order total – this quote does not represent an additional cost.	
	Net Total	$ 30,847.00

PH (888) 289-7299 FX (215) 638-5518

SUPPLEMENTAL- 1

May 28, 2015

DRAKE
REFRIGERATION
INC.

TERMS AND CONDITIONS OF SALE

1 Drake Refrigeration, Inc. ("Drake") will provide/deliver the product described in the attached Quotation. Installation will be the responsibility of Customer, and must be coordinated with the installation of the Toshiba Equipment purchased through the attached Toshiba Quotation. Once installed, Drake will inspect the product to evaluate its proper operation

2. Warranty

a. SERVICE PARTS- In warranty service parts will be invoiced pending receipt of the replaced parts previously authorized for return. After inspection of the replaced part at the factory, credit will be issued against the replacement parts providing the part was returned freight prepaid and that the part was free from abuse or misuse.

b. EQUIPMENT PARTS -DRAKE REFRIGERATION, INC. WARRANTS TO THE ORIGINAL OWNER OF THE UNIT THAT THE EQUIPMENT WILL BE FREE FROM DEFECTS IN MATERIAL AND WORKMANSHIP FOR A PERIOD OF ONE YEAR FROM THE EFFECTIVE DATE OF THE WARRANTY.

The warranty begins on the date installation is completed in accordance with the installation instructions and site plans. Improper installation may suspend the warranty until such time as all installation errors are corrected. The company's obligation under this warranty is limited to the repair or replacement of any part that shows evidence of being defective in material and workmanship and are deemed so by Drake Refrigeration, Inc., during the one year period.

The Warranty includes parts and on site labor during normal business hours (M-F 8-5 excluding holidays). Overtime charges will apply to warranty service provided outside normal business hours.

THE COMPRESSOR ONLY WILL BE WARRANTED FOR AN ADDITIONAL FOUR YEARS (TOTAL FIVE YEARS) FROM THE EFFECTIVE DATE OF THE WARRANTY PROVIDED THE EXTENDED WARRANTY IS PURCHASED WITHIN THIRTY DAYS FROM THE EFFECTIVE DATE. The compressor warranty obligates Drake Refrigeration, Inc., to replace the compressor with a comparable compressor with equal capacity, free of charge. Drake Refrigeration, Inc. assumes no responsibility for refrigerant. Defective parts will be replaced provided notice of such defect was given by the original owner within the warranty period. Drake Refrigeration, Inc. reserves the right to replace in warranty defective parts from its factory. The warranty does not cover the cost to parts substituted by field service for original equipment parts not authorized by Drake Refrigeration, Inc. Any unauthorized substitution voids the warranty.

THIS WARRANTY IS EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES. IN NO CASE WILL ANY CLAIM FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES BE APPROVED. THIS WARRANTY DOES NOT APPLY TO THE UNIT OR ANY PART THEREOF WHICH HAS BEEN SUBJECT TO DAMAGE DUE TO TRANSPORTATION.

DRAKE REFRIGERATION, INC. D/B/A/ DRAKE INDUSTRIES
2900 Samuel Drive · Bensalem, PA 19020 · Ph (888)289-7299 Fx (215) 638-5518

I accept the above Terms and Conditions of Sale with Drake Refrigeration Inc. _____

TOSHIBA
Leading Innovation

TOSHIBA AMERICA MEDICAL SYSTEMS, INC.

SERVICE AGREEMENT

DATE: 09/26/2014 QUOTE #: 60812
SID #: 30012104 SYSTEM: TITAN.000-MR

CUSTOMER LOCATION: (COMPLETE LEGAL NAME) BILLING ADDRESS:

SYCAMORE SHOALS HOSPITAL
1501 W ELK AVE
ELIZABETHTON, TN 37643

Type: INTOUCH FULL SERVICE-GB-IM-200 MR Q2 FY14 EW-PREMIER

Length Of Contract: 60 Months Start Date: TBD End Date: TBD

Total Service Agreement Price: $ 572,510.00

Payments are made 30 days in advance as follows (Please choose one):

___ Monthly $ 9,541.83 ___Annually $ 114,502.00

Toshiba will provide the following services for the equipment listed in Attachment "A", for the duration of this Agreement. All services will be provided in accordance with the attached Terms and Conditions of Service. Any changes to system configuration or services coverage noted in this agreement will require a revised quotation.

Coverage Hours:	MONDAY THROUGH FRIDAY 8:00 AM-5:00 PM EXCLUDING FEDERAL HOLIDAYS
Preventive Maintenance:	MONDAY THROUGH FRIDAY 8:00 AM-5:00 PM EXCLUDING FEDERAL HOLIDAYS
Response Time:	STANDARD 30 MINUTE PHONE RESPONSE STANDARD 4 HOUR ON-SITE RESPONSE
Uptime Guarantee:	98%
Labor and Travel Charges:	PREFERRED RATES FOR LABOR AND TRAVEL OUTSIDE OF COVERAGE HOURS.
Parts Replacement:	PARTS WILL BE REPLACED WHEN DEEMED NECESSARY BY TAMS, EXCLUDING DISPOSABLES, ACCESSORIES, OPTIONS OR UPGRADES NOT LISTED IN THE TERMS AND CONDITIONS OF THIS AGREEMENT.
Cryogens and Magnet Maintenance:	CRYOGENS ARE COVERED BY THIS AGREEMENT. ALL CRYOGEN FILLS AND MAGNET MAINTENANCE WILL BE COMPLETED AT NO ADDITIONAL CHARGE FOR THE DURATION OF THIS AGREEMENT.

This service agreement quotation is valid if it is signed by Toshiba and Customer on or before 60 days from the date of Quotation. Please return signed quotation to: Toshiba America Medical Systems, 2441 Michelle Drive, Tustin, CA 92780. Additional terms and conditions appear at the end of this quotation.

CUSTOMER ACCEPTANCE:

PRINT NAME/TITLE

Alan LeVine

PURCHASER'S SIGNATURE

DATE

TOSHIBA ACCEPTANCE:
John L. Mathews, South Zone, VP Service

PRINT NAME/TITLE

SERVICE MANAGER

January 15, 2015

DATE

TOSHIBA
Leading Innovation >>>

TOSHIBA AMERICA MEDICAL SYSTEMS, INC.

SERVICE AGREEMENT

DATE: 09/26/2014 QUOTE #: 60812
SID #: 30012104 SYSTEM: TITAN.000-MR

CUSTOMER LOCATION: (COMPLETE LEGAL NAME)

SYCAMORE SHOALS HOSPITAL
1501 W ELK AVE
ELIZABETHTON, TN 37643

BILLING ADDRESS:

Attachment A
Equipment List

This agreement includes coverage for the following items. All other options, including but not limited to lasers, injectors, power conditioners (PCDUs, VRDUs, UPSs, etc.) and other non-TAMS options, are not covered by this agreement. For additional options not listed, please contact your local Service Manager.

SYSTEM
TITAN.000(TITAN HIGH FIELD MRI SYSTEM)

COIL
MJAB-167A/P1 (TITAN BODY COIL) QTY 1
MJAJ-177A/S1 (SHOULDER SPEEDER COIL) QTY 1
MJAJ-197A/J1 (4-CHANNEL FLEX SPEEDER COIL) QTY 1
MJAJ-227A/S1 (16-CHANNEL FLEX SPEEDER LARGE COIL) QTY 1
MJAS-147A/B1 (ATLAS SPINE COIL) QTY 1
MJAH-167A/S1 (OCTAVE HEAD SPEEDER COIL) QTY 1

INCLUDED OPTIONS
MKSU-ECGU06/S1 (WIRELESS CARDIAC GATING UNIT)
MKSU-PRGK02/S1 (WIRELESS PERIPHERAL / RESPIRATORY GATING PACKAGE)
MKPA-1506/S1 (16-CHANNEL RF ELECTRONICS)

EXCLUDED OPTIONS
WSAE-HW-0002.100 (AEGIS CAD WORKSTATION SINGLE USER)
4000235-11-12 (RADIANCE PLUS BREAST IMAGING PACKAGE FOR TITAN)
PACT7853-T4-ZTM.001 (DRAKE HEAT EXCHANGER DUAL LOOP 460 FOR TITAN OR ATLAS Z)
VRDU-TITAN-U4-H (DUAL VRDU FOR TITAN U4, 480V)
WSAE-LIC-0004 (AEGIS BREAST BIOPSY LICENSE)
WSAE-HW-0004 (AEGIS LAPTOP COMPUTER (BIOPSY ONLY))
WSAE-DISP0012 (DELL 27" COLOR DISPLAY)
WSAE-SW-0002 (AEGIS BREAST PLUG-IN)
WSAE-LIC-0002 (AEGIS BREAST LICENSE)
WSAE-LIC-0001 (AEGIS BASE LICENSE)
WSAE-SW-0001 (AEGIS BASE (MM) PLATFORM)
WSAE-HW-0002 (AEGIS CAD WORKSTATION SINGLE USER)

POINT OF PURCHASE INCENTIVE
GB-IM-200 MR GB EW (07/15/14 - 09/30/14): CUSTOMER WILL RECEIVE THIS GROUP BUY PROMO PROVIDED THE EQUIPMENT ORDER IS BOOKED BY 09/30/14 AND THIS SIXTY (60) MONTH SERVICE MAINTENANCE AGREEMENT IS SIGNED AND RETURNED TO TOSHIBA AT THE TIME OF EQUIPMENT BOOKING.

ADDITIONAL COMMENTS

SUPPLEMENTAL- 1

May 28, 2015
12:25pm

IN-TOUCH SERVICES AGREEMENT
TERMS AND CONDITIONS

1. GENERAL TERMS. Unless otherwise specified on the face of this document, this Agreement will remain valid only if accepted by Customer no later than 60 days from date of submission to Customer.

2. COVERAGE. The following items are included in this Agreement.
a. Planned Maintenance Service, as specified by Toshiba. Customer will provide Toshiba service personnel with full access at the agreed upon time. Otherwise, any makeup service will be separately billed by Toshiba to Customer at Toshiba's applicable hourly rate then in effect, including round trip travel.
b. Routine System Calibration Tests, as specified by Toshiba. Customer will perform normal operator adjustments specified in the Equipment Operation Manual.
c. Remedial Maintenance Labor required to maintain the system at manufacturer's specifications during Covered Hours specified on the face of this document. Labor requested outside of the Covered Hours will be billed at Toshiba's applicable hourly rate then in effect.
d. Quality Assurance Evaluations, as specified by Toshiba. Toshiba will routinely perform quality assurance evaluations in order to assure optimum performance. Customer will provide Toshiba service personnel full access for such purposes at times mutually agreed to in advance. If applicable, Customer will run simplified Quality Assurance tests utilizing InnerVision Plus remote diagnostics.
e. Replacement of Parts, at Toshiba's cost, which fail during the term of this Agreement with the exception of the parts specified on the face of this document. Parts that are cosmetic in nature or expendable will be replaced at Customer's cost, including items such as patient pads, head cushions, and acrylic parts. Replaced parts will become the property of Toshiba. Parts replaced may be refurbished.
f. Customer may elect to upgrade / downgrade Variable Glass Tier level once a year, effective on the next contract anniversary date. This contract modification 1) will be effective on a go forward basis only, 2) may not be applied to the contract retroactively, 3) will reflect Toshiba's current pricing, and 4) must be via a written request from the Customer, presented at least 30 days prior to the contract anniversary date.
g. Travel and Living Expenses incurred by Toshiba's Customer Engineers during Covered Hours.
h. Uptime Guarantee as specified on the face of this document. Uptime guarantees are measured based on covered hours, excluding Toshiba's recognized holidays. Uptime will be calculated using the following formula:
Uptime = (Base Time – Downtime) / Base Time

Definitions: Base Time: Total covered hours. Downtime: Time when the specified imaging equipment is unavailable for scanning or diagnosing images due to Equipment malfunction, and is immediately available for service repairs. Downtime will be calculated during the Covered Hours and commence when the Customer's call is logged into the InTouch™ Center. Downtime concludes once repairs are completed and the imaging system is available for clinical use. Downtime does not include time spent for preventive maintenance, routine part replacements or repair of any malfunction caused by operator error, accidents or other elements outside the control of Toshiba, such as accidents, fires, floods, and Acts of God. The Uptime Guarantee will be voided if Toshiba is not given access to the Equipment for preventive maintenance or other types of service required during the term of this Agreement.
Uptime statistics will be measured over a 12-month period. If the Equipment fails to achieve the specified uptime percentage, the following year's services contract will be reduced by the uptime discount specified under the specific Services Agreement plan, up to a maximum of 15%.
Software Updates / Upgrades. Toshiba will furnish to Customer, free of charge for the life of the Equipment, all Toshiba software or hardware upgrades to the Equipment purchased by Customer, which are intended to correct a safety risk. Software updates offering enhancements to previously purchased software features are covered under this service agreement, if they do not require hardware modifications or additions. Software upgrades providing new features or capabilities not originally purchased, will be made available for purchase by Customer upon request when compatible with the originally purchased hardware. Toshiba retains the sole right to determine whether a software release is considered an update or an upgrade for which the Customer will be charged.

The above items will be performed only during the Covered Hours stated on the face of this document. Service required outside these hours will be billed at Toshiba's differential rates in effect at the time such items are provided to Customer.

3. ITEMS EXCLUDED. The following items are excluded from this Agreement unless otherwise indicated on the face of this document.
a. Customer operation instructions.
b. Adding or removing accessories, attachments, or other devices, and remedial services necessary to repair accessories.
c. Services connected with Equipment movement or relocation.
d. Problems caused by external sources, including the incoming power supply.
e. Increase in service time resulting from operator neglect or failure to follow operation instructions.
f. Repair or damage from accident or any cause other than ordinary use.
g. Rigging and handling, removal, modification or reconstruction of a wall, partition, ceiling or any other portion of the facility arising from repair, replacement or substitution of Equipment or parts of it.
h. Chiller maintenance or repair.
i. Expendable materials or accessories (for example, straps, foam cushions, and other similar items).
j. Problems caused by modifications, maintenance or repairs of the equipment or software not performed by Toshiba.
k. Storage facilities for spare parts, tools and supplies.

Performance of services not included in this Agreement will be charged in accordance with Toshiba's prices in effect at the time such services are provided to Customer.

4. CUSTOMER RESPONSIBILITIES. During the term of this Agreement, Customer agrees to maintain the site and environment (including temperature and humidity control, incoming power quality, and fire protection system) in a condition suitable for operation of the Equipment; ensure the Equipment is used at all times in accordance with the requirements of the Equipment Operation Manual by properly qualified and appropriately licensed personnel; and make normal operator adjustments to the Equipment as specified in the Equipment Operation Manual. In addition, Customer agrees to provide and maintain a dedicated broadband Internet access node suitable for connection to Customer's network and allow access to Toshiba's VPN for Toshiba's use for InnerVision Plus™, if applicable. Failure to provide an appropriate VPN connection may result in a reduction in the uptime guarantee commitment and an increase in service charges for the Equipment.

5. REMOTE DIAGNOSTICS (INNERVISION PLUS). Toshiba may install certain equipment and parts ("InnerVision Plus") at Customer's site in order to perform remote diagnostics on the Equipment. Customer hereby acknowledges that Toshiba retains title to InnerVision Plus. Toshiba will remove the InnerVision Plus upon termination or expiration of this Agreement. Customer will not remove, modify, or use or allow third parties to use InnerVision Plus without Toshiba's prior written consent. Customer will be responsible and will promptly pay for any loss or damage to InnerVision Plus unless caused by Toshiba's sole negligence.

6. GEOGRAPHICAL EQUIPMENT OR COVERAGE. Toshiba must be notified in writing at least ninety (90) days prior to relocation of Equipment to a site that is fifty (50) miles or greater from the unit's base site specified on the face of this document so that Toshiba may adequately address manpower needs to maintain the site.

7. ACCEPTANCE BY TOSHIBA. This Agreement will not be binding on Toshiba unless and until it is accepted by Toshiba as evidenced by the signature of an authorized representative of Toshiba on the face of this document. Toshiba's acceptance is expressly made conditional upon Customer's assent to the terms and conditions in this document. All different or additional terms and conditions which may be contained in Customer's bid documents, purchase order or any other documents furnished by Customer are hereby objected to and deemed material unless accepted in writing by an authorized representative of Toshiba. Toshiba will give Customer a fully executed copy of this Agreement upon acceptance by Toshiba.

Toshiba's service of Equipment under this Agreement is available only if the effective date of this Agreement follows within 15 calendar days of (a) the expiration of an applicable warranty period covering such Equipment, or (b) the expiration of an applicable Toshiba Services Maintenance Agreement. If the effective date is outside such 15-day period, Toshiba must be given the right to inspect the Equipment and repair and restore the Equipment to proper working order in accordance with Toshiba's specifications before this Agreement may become effective. All service labor and parts furnished for such repair and restoration will be charged to Customer at Toshiba's prevailing rates.

8. TERMINATION. This Agreement will terminate upon the expiration date specified on the face of this document. Customer may not terminate this Agreement before its expiration unless (a) Customer sells, discards or otherwise completely discontinues using the Equipment, or (b) Customer exchanges the Equipment for another new Toshiba Equipment, or (c) Toshiba substantially fails to perform any of its material obligations specified in this Agreement. In the case of termination for the reasons stated in (a) or (b) above, the termination will be effective 90 days from the date of Customer's written notice to Toshiba of termination. If Customer elects to terminate for the reasons stated in (c) above, before such termination, customer must notify Toshiba in writing of the breach and of its intent to terminate this Agreement if such breach is not corrected within thirty (30) days from Toshiba's receipt of the notice of breach. If Customer elects to terminate this Agreement before its expiration for any reason other than the reasons set forth in (a) through (c) above, or if Toshiba terminates this Agreement due to Customer's default pursuant to Section 16, Customer must pay Toshiba, as liquidated damages, an amount equal to 25% of the total service amounts payable under this Agreement for the term remaining as of the date of termination.

9. ACCESS TO EQUIPMENT. Customer will afford unrestricted and safe access to the Equipment for Toshiba's representatives and will cooperate with Toshiba's representatives in their performance of the services under this Agreement. If Customer fails to provide such access and cooperation, Toshiba will be relieved of its obligations under this Agreement, including, without limitation, the Uptime Guarantee.

10. CONSUMABLE ITEMS. Customer will provide necessary consumable items and processing facilities required by Toshiba in performance of the services under this Agreement at no charge to Toshiba.

11. END OF MAINTENANCE SUPPORT ANNOUNCEMENT. In the event that Toshiba makes a future general commercial announcement that services contracts will no longer be offered for an item of Equipment or Equipment component covered by this Agreement, then upon no less than 12 months prior written notice to the Customer, Toshiba may, at their option, remove any such item(s) of Equipment or Equipment component(s) from service coverage under this Agreement, with an appropriate adjustment of charges hereunder, without otherwise affecting this Agreement.

12. COMPENSATION AND TAXES. For the services and materials provided under the Agreement, Customer will pay Toshiba the total amounts specified on the face of this document for each system covered. For fixed contracts, this sum will be paid in advance, based on the chosen installments specified on the face of this document. For variable contracts, Toshiba representatives will be given access to usage information and the Equipment for the purpose of measuring variable use. Each month Toshiba will invoice Customer and Customer will pay the higher of the minimal or actual usage for the preceding period based upon the data from the site. The amounts specified on the face of this document do not include sales, use or other similar taxes. Customer will pay any such taxes, unless a tax exemption certificate acceptable to the applicable taxing authorities is provided to Toshiba. All invoices paid after due date will be assessed a late payment charge of the lesser of 1.5% per month or the maximum rate permitted by law.

13. ~~CPI ADJUSTMENT. The service fees payable under this Agreement may be increased up to three percent annually at Toshiba's sole discretion. The increase is effective on the anniversary date of the Agreement starting with the first anniversary. The customer will be notified by Toshiba at least 60 days prior to any adjustment. The increase will then be automatically added to the first payment following the anniversary date.~~

14. ASSIGNMENT. Neither Customer nor Toshiba may assign this Agreement without the prior written consent of the other.

15. SOFTWARE. All rights and interest in any software that may be furnished under this Agreement, and any updates and enhancements to it, will remain the property of Toshiba. Such software is being furnished to Customer under a non-exclusive license. Customer will not decompile, modify, copy, reproduce, or transcribe the software, nor allow third parties to use the same without Toshiba's prior written consent. Upon Toshiba's request, Customer will execute a software license contract, in a form designated by Toshiba.

16. DEFAULT. Upon default by Customer, any affiliate or parent of Customer, any partner of Customer, or any principal of Customer in payment or performance of any obligation under this Agreement or any other agreement with Toshiba, whether entered into before or after the date of this Agreement (including, without limitation, any agreement for sale of equipment to Customer) will, at the sole option of Toshiba, if default is not cured within ten (10) days after written notice of the default, constitute a default of this Agreement. In such event, Toshiba may at its option (a) suspend performance under this Agreement until all such defaults have been cured, (b) terminate this Agreement in which case Customer shall pay Toshiba all amounts that are due for the period prior to the termination date (or the suspension date if the Agreement was suspended prior to termination), as well as liquidated damages equal to 25% of the total service amounts payable under this Agreement for the term remaining as of the termination date (or suspension date if the Agreement was suspended prior to termination), and/or (c) exercise any other remedies allowed by law. If this Agreement is suspended, Customer will be required to pay the following as a condition to Toshiba resuming service: (i) all past due amounts for the period prior to the suspension, and (ii) the liquidated damages amount set forth in Section 8 above for the period of the suspension.

17. ATTORNEY'S FEES AND COSTS. In the event of any legal proceeding involving any party to this Agreement against the other relating to the subject matter of this Agreement, the prevailing party in such proceeding will be entitled to recover attorney's fees, expert fees, collection agency fees and court costs against the non-prevailing party.

18. CIRCUMSTANCES BEYOND CONTROL. Toshiba will not be liable for non-performance or delay in performance resulting directly or indirectly from any occurrence beyond Toshiba's control, including without limitation, strikes or other labor actions, Acts of God, war, accidents, fires, floods, other catastrophes, inclement weather, transportation, delays caused by Toshiba's suppliers, inability to obtain replacement parts, or laws, regulations, or acts of any governmental agency. The foregoing provision will apply even though such cause may occur after performance of the obligations of Toshiba under this Agreement has been delayed for other causes.

19. DISCLAIMER OF WARRANTIES. TOSHIBA MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY, OR WARRANTY OF FITNESS FOR PARTICULAR PURPOSE WITH RESPECT TO ANY OF THE SERVICES AND PARTS FURNISHED UNDER THIS AGREEMENT.

20. LIMITATION OF LIABILITY AND OF REMEDY. TOSHIBA WILL NOT UNDER ANY CIRCUMSTANCES BE LIABLE FOR CONSEQUENTIAL, SPECIAL, INCIDENTAL, OR EXEMPLARY DAMAGES OR ECONOMIC LOSS ARISING OUT OF OR RELATED TO THIS AGREEMENT, EVEN IF TOSHIBA IS APPRISED OF THE LIKELIHOOD OF SUCH DAMAGES OCCURRING. THIS LIMITATION WILL NOT APPLY TO CLAIMS FOR PERSONAL INJURY OR DEATH CAUSED BY TOSHIBA.

21. EXPORT RESTRICTIONS. This Agreement involves products, and/or technical data that may be controlled under the U.S. Export Administration Regulations and may be subject to the approval of the U.S. Department of Commerce prior to export. Any export or re-export by Customer, directly or indirectly, in contravention of such Regulations is prohibited.

22. FACSIMILE SIGNATURES. This agreement may be executed in one or more counterparts, each of which shall constitute an original and all of which taken together shall constitute one and the same Agreement. Facsimile signatures (signed copies transmitted via fax or electronic file) shall be of equal effect and validity as signatures on original copies, so long as the electronically transmitted copy includes the printed name and title of the signatory of the Agreement.

23. ENTIRE AGREEMENT. This Agreement contains the entire agreement between the parties and supersedes all prior or concurrent agreements between the parties, whether oral or written, relating to its subject matter. The provisions of this Agreement may not be modified unless in writing and executed by both parties.

SUPPLEMENTAL- 1

May 28, 2015
12:25pm

TERMS AND CONDITIONS
AMENDMENT TO SERVICE AGREEMENT

This Terms and Conditions Amendment to Service Agreement Quote #60812 (this "Amendment"), is made effective as of the 14th day of January, 2015 (the "Effective Date") by and between Mountain States Health Alliance d/b/a Sycamore Shoals Hospital ("MSHA") and Toshiba American Medical Systems, Inc.(hereinafter "Vendor").

MSHA. "MSHA" refers to the Mountain States Health Alliance affiliate with whom the Vendor will contract (the "Agreement") for the Vendor to provide goods or perform services. An affiliate shall mean an entity controlled by, controlling, or under common ownership with MSHA.

WHEREAS, MSHA and Vendor entered into Service Agreement quote #60812 dated September 26, 2014 (the "Agreement"); and

WHEREAS, MSHA and Vendor desire to amend the Agreement as provided herein.

NOW, THEREFORE, in consideration of the mutual covenants herein stated and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged and agreed, the parties hereby amend the Agreement as follows:

A. **Amendments.** The following terms and conditions are hereby added to the Agreement and incorporated therein:

1. **Vendor Certification and Conduct.** All Vendor employees, agents or representatives (collectively "personnel") providing services hereunder shall complete MSHA's Vendor Certification Program, orientation and badging process. While performing services in MSHA's facility, Vendor personnel shall wear appropriate Vendor identification badges and shall not hold themselves out as employees or personnel of MSHA. While present on MSHA premises or accessing MSHA Information Systems, Vendor personnel will be subject to the policies and procedures of MSHA. MSHA may exercise its discretion and remove or bar any Vendor personnel who poses an immediate risk of harm to self, others, or property or who is deemed to be conducting oneself contradictory to the MSHA's mission.

2. **Debarment and Suspension.** Vendor hereby certifies that neither it nor any of its personnel providing services on behalf of MSHA is (a) a listed vendor in the Federal General Services Administration's "List of Parties Excluded from Federal Procurement or Nonprocurement Programs" in accordance with Presidential Executive Orders 12549 and 12689, "Debarment and Suspension;" (b) listed in the Office of Inspector General's "List of Excluded Individuals/Entities (LEIE)" pursuant to 42 U.S.C. 1320a-7; or (c) ever been convicted of a criminal offense related to healthcare. Vendor shall notify MSHA immediately in the event that any of the aforementioned certifications becomes untrue or if Vendor is the subject of government investigation that could lead to one or more certifications being untrue. Vendor shall promptly remove any personnel from providing service on behalf of MSHA hereunder in the event such certifications become untrue with respect to such individual. This Agreement shall automatically terminate in the event that any of the certifications in this section are untrue with respect to Vendor.

3. **EEO Compliance.** Unless exempted by the rules and regulations of the Secretary of Labor, Vendor will comply, and require that its subcontractors certify compliance, with Executive Order 11246, as amended by Executive Order 11375; Section 503 of the Rehabilitation Act of 1973, as amended; the Vietnam Era Veteran Readjustment Assistance Act of 1974, as amended; and

Executive Order 11625, as amended; and the rules and regulations issued thereunder. The parties do not intend that this provision confer any rights on any third party.

4. **Code of Ethics and Business Conduct.** Vendor acknowledges it has received a copy of the Code of Ethics and Business Conduct of MSHA found at: http://www.msha.com/uploads/pdf_files/MSHACodeofEthics.pdf Vendor agrees that it and Vendor personnel providing services on behalf of MSHA pursuant to this Agreement will either (i) abide by its terms and provisions; or (ii) in the event the Vendor has a substantially similar Code of Ethics and Business Conduct, abide by Vendor's Code of Ethics and Business Conduct.

5. **Access to Records.** Upon the written request of the Secretary of Health and Human services or the Comptroller General or any of their duly authorized representatives, Vendor and any of its affiliates providing services with a value or cost of $10,000 or more over a twelve (12) month period shall make available to the Secretary the contracts, books, documents and records that are necessary to verify the nature and extent of the cost of providing such services. Such inspection shall be available up to four (4) years after the rendering of such services.

6. **Payment Terms.** MSHA shall render payment within forty-five (45) days of the date of MSHA receipt of a written invoice for the goods or services from the Vendor. All invoices for payment shall be in U.S. Dollars and shall include the Purchase Order number, and an itemization of charges and fees, total value of Invoicing to date and value of the current invoice. Invoices for payment not including such information may be returned to Vendor without payment.

7. **Quality Requirements for Services.** Vendor shall provide all services required under this Agreement in a diligent manner consistent with (i) the scope of services specified in the Agreement; (ii) applicable practices and standards of diligence, care and skill currently recognized in Vendor's industry; and (iii) applicable law.

8. **Infringement Indemnity.** Vendor will defend, at its own expense, any legal action brought against MSHA to the extent that it is based on a claim that any licensed materials ("Licensed Materials") granted to MSHA by Vendor infringes a United States patent, copyright, trade secret or other intellectual property right of a third party, and Vendor will pay any costs, fees, expenses and final judgment against MSHA in any such action if attributable to any such claim or incurred by MSHA through settlement of such claim. However, such defense and payments are subject to the conditions that MSHA must: (i) notify Vendor promptly in writing of such claim, (ii) permit Vendor to have sole control of the defense, compromise or settlement of such claim, including any appeals, and (iii) fully cooperate with Vendor in the defense or settlement of such claim. Should the Licensed Material become, or in Vendor's opinion be likely to become, the subject of any such infringement claim, MSHA shall permit Vendor, at Vendor's option and expense, to (a) procure for MSHA the right to continue using the Licensed Material, (b) replace or modify the Licensed Material so that it becomes non-infringing, or (c) terminate the right to use the Licensed Material, upon which termination MSHA agrees to promptly destroy all copies of the licensed material and certify the same to Vendor, whereupon Vendor will refund MSHA's license fee on a pro rata basis for the remainder of the license term. Vendor shall have no liability for any claim of patent, copyright or trade secret infringement that is based on (x) the use or combination of the Licensed Material with software, hardware or other materials not recommended by Vendor, provided such infringement would not have arisen but for such use or combination, (y) use of the Licensed Materials in a manner other than that for which it was designed or contemplated as evidenced by Vendor's documentation or agreement with MSHA, or (z) any unauthorized modification by MSHA or a third party on behalf of MSHA.

9. **General Indemnity.** Vendor agrees to and does hereby defend, indemnify and hold harmless MSHA and each of its affiliates, successors, assigns, directors, officers, agents and employees ("MSHA Indemnitees") from and against any and all liabilities, demands, losses, damages, costs, expenses, fines, amounts paid in settlements or judgments, including without limitation, costs, reasonable attorneys' fees, witnesses' fees, investigation expenses, costs of management time, any and all out-of-pocket expenses, any punitive or consequential damages, and all other expenses and costs incident thereto (collectively referred to as "Damages") resulting from: (i) any claim, lawsuit, investigation, proceeding, regulatory action, or other cause of action, which may be suffered by reason of any loss, damage, death, injury, and/or other reason arising out of or in connection with products furnished or services performed by Vendor pursuant to this Agreement ("Injury"), unless the Injury was caused solely by reason of MSHA's negligence or willful misconduct; or (ii) the breach by Vendor of the warranties, representations or covenants contained in this Agreement or in materials furnished by Vendor.

10. **Insurance.** In the event Vendor is performing services on behalf of MSHA, Vendor shall, during the term of the Agreement, maintain at its own expense, (i) workers' compensation insurance coverage for Vendor's employees in each state where services are performed, pursuant to such state's requirements; (ii) commercial general liability insurance with MSHA listed as an additional insured; and (iii) professional liability insurance in the event that Vendor provides any professional services. Such general and professional liability insurance may be provided on either an occurrence or claims-made basis, and shall provide limits of liability in the minimum amount of one million dollars ($1,000,000) per occurrence with an annual aggregate of three million ($3,000,000). Notwithstanding the foregoing, in the event Vendor performs professional services pursuant to the Agreement within Virginia, Vendor shall maintain per occurrence/per claim professional liability insurance limits consistent with the Virginia medical malpractice limit of liability under Virginia Code Section 8.01-581.15 (as amended or superseded), with aggregate limits three times the per occurrence / per claim limit.

    If any of Vendor's liability insurance coverage required above is maintained on a claims made basis, such insurance shall continue throughout the term of the Agreement; and upon the termination, expiration or non-renewal of the Agreement, or the expiration or cancellation of the insurance, Vendor shall purchase and maintain coverage for claims presented after the termination, expiration or non-renewal of the Agreement that arise from acts or events occurring during the term of the Agreement. Upon MSHA's request, Vendor shall provide MSHA with a copy of all such policies and/or certificates of insurance satisfactory to MSHA, evidencing the existence of all coverage required hereunder. Vendor shall require its insurance carriers or agents to provide MSHA, and Vendor shall also provide MSHA with not less than thirty (30) days' prior written notice in the event of a change in such policies.

11. **Independent Contractor.** No relationship of employer and employee is created by this Agreement, it being understood that Vendor and all its personnel providing services pursuant to this Agreement are and will act hereunder as independent contractors with respect to MSHA. Vendor's personnel shall not be employees of MSHA and shall not have any claim under this Agreement or otherwise against MSHA for vacation pay, sick leave, retirement benefits, social security contribution, worker's compensation, disability or unemployment insurance benefits or any other employee benefit of any kind. Vendor shall hold MSHA harmless against all liability and loss in connection with payment or nonpayment of any federal, state and local taxes or contributions imposed or required under employment insurance, Social Security and income tax laws or any other employment-related laws, including requirements for affordable health care insurance under the Affordable Care Act, with respect to personnel furnished to MSHA by Vendor hereunder.

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12. **Confidentiality.** During the term of this Agreement and surviving its expiration or termination, Vendor will regard and preserve as confidential all information related to the business of MSHA and its affiliates, clients and patients that may be obtained as the result of this Agreement. Vendor will not, without first obtaining MSHA's prior written consent, disclose to any person, firm or enterprise or use for its benefit any information relating to the pricing methods, processes, financial data, lists, apparatus, statistics, programs, research, development or related information of MSHA or their affiliates concerning their past, present or future business activities or plans, and results or terms of the sale of products or provision of services by Vendor under this Agreement. This confidentiality obligation does not apply to: (a) information that is publicly known prior to the disclosure or becomes publicly known through no wrongful act of the Vendor; (b) information that was in lawful possession of the Vendor prior to the disclosure and was not received as a result of any breach of confidentiality with respect to MSHA or its affiliates; (c) information that was independently developed by Vendor outside the scope of this Agreement, or (d) information which Vendor is required to disclose pursuant to court order or regulatory agency request. In the event of a request for disclosure falling under part (d) above, immediate notice of such request shall be provided to MSHA in order to provide an opportunity to oppose such request for disclosure. MSHA shall have the right to use Vendor pricing information on products and services for MSHA's internal analyses and may disclose such information to group purchasing organizations in which MSHA participates, counsel, consultants, advisors and potential successors in interest and purchasers.

13. **Protected Health Information.** Vendor and Vendor's personnel shall maintain the confidentiality of all patient records and data, including, without limitation, individually identifiable health information (the "Protected Health Information" or "PHI") and obtain appropriate authorization prior to any disclosure of such records and data. All title to medical records, charts, and patient files and data shall be and remain the sole property of MSHA. Notwithstanding any provision herein to the contrary, Vendor acknowledges and agrees that neither it, nor any of its personnel shall receive access to any patient information beyond that minimum amount of information necessary to accomplish the intended purpose of this Agreement. Vendor agrees that the PHI shall only be used by Vendor and its personnel for the purposes of performing pursuant to this Agreement and shall not be used for marketing, or any other purposes whatsoever, and shall only be disclosed in accordance with the terms hereof. To the extent that Vendor is a business associate, as that term is defined within the Health Insurance Portability and Accountability Act of 1996 and its privacy and security regulations promulgated pursuant thereto, Vendor shall, prior to obtaining access to PHI, execute a separate business associate agreement with MSHA that describes Vendor's obligations with regard to the possession and use of such PHI.

14. **Performance Expectations; Monitoring; Corrective Action:** In the event Vendor performs clinical services on behalf of MSHA, MSHA shall monitor the quality of services provided hereunder through appropriate methods, which may include direct observation of services provided by Vendor, audit of documentation, review of incident reports, review of performance data, review of input from MSHA's staff, review of patient satisfaction surveys, and/or review of results of risk management activities. In the event MSHA determines that Vendor is not meeting any of the requirements set forth in this Agreement, MSHA shall notify Vendor, and Vendor shall cooperate with MSHA in the development and implementation of a corrective action plan. Vendor's failure to comply with any such corrective action plan may result in termination of this Agreement. Notwithstanding anything in this Agreement to the contrary, MSHA reserves the right to terminate the Agreement immediately in the event Vendor's actions adversely impact patient care and safety.

15. **Notices.** Notices under this Agreement shall all be in writing, effective as follows: (a) three (3) days after depositing U.S. certified or registered mail with return receipt, postage prepaid, in the mails; (b) one (1) day after sending by overnight delivery through a nationally recognized courier service; or (c) upon receipt by personal or same-day courier delivery. Unless stated otherwise provided in writing by Vendor to MSHA, notices to Vendor shall be sent to Vendor's principal address or the address specified in the Agreement. Unless stated otherwise provided in writing by MSHA to Vendor, notices to MSHA shall be sent to MSHA's address stated in the Agreement and to:

Mountain States Health Alliance
Legal Department
400 North State of Franklin Road
Johnson City, TN 37604-6094

16. **Notices for Recalls, Alerts, and Advisories.** Notices specifically for recalls, alerts, and advisories should be sent to MSHA - The Recall, Alert and Advisory Center (TRAAC) at: TRAAC@msha.com

17. **Governing Law and Venue.** The performance of the parties under this Agreement shall be controlled and governed by the laws of the state in which the MSHA facility is located, excluding choice or conflicts of law provisions that would cause the application of the domestic substantive laws of any other jurisdiction. In the event of any dispute arising herein, including the collection of fees, the jurisdiction and venue of all legal proceedings shall be in the in the state or federal courts where the MSHA facility is located.

B. Conflict. To the extent that this Amendment conflicts with the Agreement or any other amendment, this Amendment shall govern.

C. Miscellaneous. This Amendment may be executed simultaneously in two or more counterparts (including facsimile, "pdf" and other electronic copies) each of which shall be deemed an original and all of which together shall constitute but one and the same instrument. Capitalized terms not defined herein shall have the meanings ascribed to them in the Agreement, unless otherwise specified herein. Except as set forth in this Amendment, no other changes are being made to the Agreement and the Agreement shall remain in full force and effect. The recitals are hereby incorporated into this Amendment by reference. "MSHA" refers to Mountain States Health Alliance and/or the MSHA affiliate with whom the Vendor will contract (the "Agreement") for the Vendor to provide goods or perform services. An affiliate shall mean an entity controlled by, controlling, or under common ownership with MSHA, and for this purpose "control," "controlling" and "controlled by" shall mean the ownership and control of more than fifty percent (50%) of the ownership interest in the entity, or the right to direct or control the management or affairs of the entity by contract or similar arrangement.

IN WITNESS WHEREOF, each party represents that it has caused this Amendment to be executed and delivered by an officer of such party, duly authorized, as of the date first above written.

[Remainder of page intentionally left blank; signature page to follow]

SUPPLEMENTAL- 1

APPROVED BY MSHA
LEGAL DEPARTMENT
RKS

MOUNTAIN STATES HEALTH ALLIANCE d/b/a
SYCAMORE SHOALS HOSPITAL

By: _____

Name: Alan Levine

Title: CRO

Date: 1-25-15

TOSHIBA AMERICA MEDICAL SYSTEMS, INC:

By: _____

Name: John L. Mathews

Title: South Zone, VP Service

Date: January 15, 2015